IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

SEAGEN, INC.,	(	CAUSE NO. 2:20-CV-337-JRG
	)	
Plaintiff,	(	
	)	
vs.	(	
	)	
DAIICHI SANKYO CO., LTD.,	(	
	)	
Defendant, and	(	
	)	
ASTRAZENECA PHARMACEUTICALS, LP and ASTRAZENECA UK, LTD.,	(	
	)	MARSHALL, TEXAS
	(	APRIL 7, 2022
Intervenor-Defendants.	)	8:30 A.M.

VOLUME 4

TRIAL ON THE MERITS

BEFORE THE HONORABLE RODNEY GILSTRAP
UNITED STATES CHIEF DISTRICT JUDGE
and a jury

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EXAMINATION

THE COURT: Be seated, please.

Counsel, as you're aware, during the final portion of yesterday's segment of the trial, Juror No. 4 became nauseated. We took a recess, and then we recessed for the day about an hour earlier than we might otherwise have because of that.

She's indicated to the deputy in charge that she's been equally nauseated and feeling bad all night long, and, consequently, I'm going to excuse her and we're going to go forward with our six remaining jurors. And I'll advise the jury of that once they come into the courtroom so they'll know why their cohort is not with them.

All right. Are the parties prepared to read into the record those items on the list of preadmitted exhibits used during yesterday's portion of the trial?

MS. STAURING: Yes, Your Honor.

THE COURT: Please proceed.

MS. STAURING: Good morning, Your Honor. Jessica Stauring on behalf of Defendants.

MR. HAN: Chris Han on behalf of Plaintiffs.

THE COURT: Good morning. Please go ahead.

MS. STAURING: The parties have agreed to read the following exhibits into the record. The following exhibits are all: PX, 30, 155, 164, 169, 170, 260, 261, 263, 299, and 843.

The following exhibits are all DX: 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 57, 58, 59, 60, 61, 62, 64, 69, 70, 71, 74, 75, 77, 78, 79, 82, 83, 85, 86, 88, 89, 92, 93, 96, 107, 108, 110, 112, 114, 115, 118, 123, 124, 125, 126, 127, 128, 129, 134, 136, 140, 142, 145, 153, 155, 157, 158, 159, 161, 163, 164, 166, 167, 168, 169, 172, 173, 176, 177, 179, 180, 181, 183, 185, 186, 190, 191, 195, 199, 202, 205, 208, 213, 214, 215, 216, 217, 218, 219, 220, 221, 223, 225, 226, 233, 235, 236, 237, 242, 243, 244, 246, 247, 250, 251, 252, 281, 461, 495, 538, 571, 691, 692, 693, 940, and 941.

That's all, Your Honor.

THE COURT: Any objection to that rendition from the opposing party?

MR. HAN: No, Your Honor.

THE COURT: Is there anything else to read into the record from yesterday, counsel?

MR. HAN: Nothing further, Your Honor.

THE COURT: Thank you very much.

MS. STAURING: Thank you.

THE COURT: Ms. Ainsworth, I was told by your co-counsel that you have an additional proffer you wanted to make?

MS. AINSWORTH: Yes, Your Honor, if I may.

THE COURT: Please proceed. I'd like to get started with the jury as soon as possible.

MS. AINSWORTH: Yes, Your Honor.

Your Honor, Defendants earlier yesterday offered -- requested to be able to present certain deposition testimony of Seagen's corporate representative, Dr. Peter Senter, on certain key issues in the case, and requested that that corporate representative testimony be played during Defendant's case in chief. This was after Doctor Senter had testified live in the Plaintiff's case in chief.

The Court ruled that Defendants should not present this 30(b)(6) deposition testimony in our case due to potential jury confusion, and the Court offered Defendants the opportunity to examine him live rather than present the deposition testimony.

And Defendants just respectfully state that we should be allowed to offer the 30(b)(6) deposition testimony for two reasons: First, under Rule 32(a)(2) and (3), the corporate representative testimony is usable for any purpose without regard to the witness' availability; and, second, because his testimony during the Plaintiff's case in chief was in his individual capacity rather than a corporate representative. He was not presented in this case as Seagen's corporate representative. Instead, they've had an individual representative at trial which is their -- at counsel table which is their right.

However, we should have the right to present this

corporate testimony of Seagen through that deposition rather than having to re-examine him again in his individual capacity. And we have the deposition cuts. I will have the physical copies that I can tender to the Court on the next break.

THE COURT: Does that complete your proffer?

MS. AINSWORTH: It does, Your Honor.

THE COURT: Let me just add for optional completeness, the Court did not preclude the Defendants from presenting Doctor Senter in their case in chief. The Court merely advised the parties that, in the Court's view, it would create unnecessary confusion with the jury since Doctor Senter testified live in the Plaintiff's case and Doctor Senter has personally been present in the courtroom throughout the trial and is present sitting in the courtroom right now.

The Court observed that there would be no problem with the same questions and answers set forth in his deposition being asked to him live so that the same testimony could be presented and it could be clearly made clear to the jury that that testimony was in a different capacity.

It was not a matter of whether he could -- or whether that testimony could or could not be presented, but merely the form of presentation because the Court in the early portion of the trial in its preliminary instructions to the jury made it clear in explaining what a deposition was, that depositions

were presented when people could not be present to testify live.

And the Court, exercising one of its paramount obligations to prevent unnecessary confusion with the jury, merely indicated to the Defendant that if they chose to call Doctor Senter in their case in chief, the Court preferred and would direct that they do it with him personally on the witness stand, asking the same questions and seeking the same information that they otherwise purported to play by deposition clips.

And that's my view of the interplay that took place. I accept your proffer, and we'll go from there.

MS. AINSWORTH: Thank you, Your Honor.

THE COURT: All right. Is there anything from Plaintiff?

MR. HILL: Your Honor, you stated the basis for the Court's exclusion. I'm happy to state our position with regard for the record if the Court wants to hear it.

THE COURT: I just generally asked if you had anything else before I brought in the jury. If you would like to respond to the proffer, you may.

MR. HILL: Thank you, Your Honor.

THE COURT: It's your option.

MR. HILL: Thank you, Your Honor.

I will state one additional issue. Under Rule 611,

obviously the Court has the discretion to do exactly what it did. The material that was going to be offered was cumulative of testimony that had already been elicited live from Doctor Senter. Defendants elected not to recall him live.

And as the Fifth Circuit recognized *Brazos River Authorities versus GE Ionics*, district courts are reluctant to allow the reading into evidence of a Rule 30(b)(6) deposition if a witness is available to testify at trial. That is precisely the situation we had here, the Fifth Circuit has said the Court is perfectly within its discretion to do what it did, and we'd like that noted for the record.

THE COURT: And just to avoid any doubt in the record, I am looking at Doctor Senter physically sitting in the courtroom where he has been present throughout the entirety of the trial.

All right. Is there anything else we need to take up before we bring in the jury?

MR. HILL: No, Your Honor.

MR. DACUS: No, Your Honor.

THE COURT: All right. Mr. Ratliff, you may go to the podium and prepare for your redirect.

Doctor Lambert, if you'll come forward and return to the witness stand, sir. As I know you're aware, let me remind you you're under oath.

THE WITNESS: Yes. Thank you, Your Honor.

THE COURT: You have something, Mr. Chivvis, or are you just getting up for the jury?

MR. CHIVVIS: I'm just getting up for the jury so I'm not scrambling.

THE COURT: All right. While they're getting situated, bring in the jury, please, Mr. Johnston.

(Whereupon, the jury entered the courtroom.)

THE COURT: Good morning, ladies and gentlemen. Welcome back. Please have a seat.

Members of the jury, as you're well aware, you are now down to six from seven. Miss Gabel, No. 4, as you are aware, experienced some nausea yesterday toward the end of the day. We stopped a little bit early because of that. I understand she is substantially the same overnight.

We can proceed without seven jurors. Six is an adequate number to return a verdict, but it's necessary to have six jurors. Given those circumstances, I've excused Miss Gabel, and you six will go forward as the jury in the case. I just want you to be aware of that so there's no question about why you're missing one of your members who was here yesterday.

All right. We'll return to the testimony of Dr. John Lambert. When we ended yesterday's portion of the trial, Defendants were about to engage in redirect examination of the witness, and that's where we'll pick up with Mr. Ratliff.

You may proceed, counsel.

MR. RATLIFF: Thank you, Your Honor.

JOHN LAMBERT, PhD., PREVIOUSLY SWORN,

REDIRECT EXAMINATION

BY MR. RATLIFF:

Q. Good morning, Doctor Lambert.

A. Good morning, counsel.

Q. Doctor Lambert, do you recall yesterday that Seagen's counsel asked you whether the claims of the '039 Patent used the word 'only' in connection with the G and F tetrapeptide limitation?

A. I do recall that.

Q. Well, let's bring up DX 1 and let's turn to the last page which shows the claims.

Now, focusing on claim 1, Doctor Lambert, can you tell us whether the claim requires that each amino acid in the tetrapeptide is either G or F?

A. Yes, it does.

Q. And, Doctor Lambert, what's the significance of what you just told us as to the question regarding whether the claim requires a G/F-only tetrapeptide?

A. The claim requires a G/F-only tetrapeptide.

Q. Now, let's bring up one of your slides, slide 94.

Doctor Lambert, yesterday Seagen's counsel pointed you to Seagen's original 2004 application and asked about G and F and whether they were listed among many other amino acids. Do you

recall that?
A. I do recall that.
Q. Now, did Seagen's counsel point you to any disclosure in that original 2004 application that showed a tetrapeptide where each amino acid must be G or F?
A. No.
Q. Now, Doctor Lambert, let's bring up DX 104 -- or slide 104.
Now, Doctor Lambert, in slide 104, do you recall that you were asked a question by Seagen's counsel and the question related -- do you recall that the question related to when did Seagen first file patent claims to an ADC with a G/F-only tetrapeptide?
A. Yes, I recall that.
Q. And does this slide refresh your recollection as to when that happened?
A. It does.
Q. And can you tell us when that happened, sir?
A. In July 2019.
Q. Now, Doctor Lambert, and do you recall that you were asked questions about Seagen's 2004 original application by counsel?
A. I do.
Q. And did that 2004 application ultimately publish and be issued as a patent?

A. Yes.
Q. Now, Doctor Lambert, do you recall yesterday that Seagen's counsel pointed you to the sequence GFLG that's one of the three examples of the tetrapeptides in the '039 Patent?
A. Yes, I recall that.
Q. Now, Doctor Lambert, is that sequence a G/F-only tetrapeptide?
A. No, it is not.
Q. And does the original 2004 application by Seagen include any example of an ADC with a GFLG tetrapeptide?
A. No, it does not.
Q. Now, do you recall that Doctor Bertozzi also testified that a skilled person would have started with a GFLG in the 2004 application and modified it to arrive at a G/F-only tetrapeptide?
A. I do remember that.
Q. And, Doctor Lambert, can you tell us whether or not you believe the skilled person in 2004 would have made that modification as Doctor Bertozzi suggests?
A. No, I don't believe a skilled person would do that.
Q. And can you explain to us why, Doctor?
A. Well, the -- that GFLG tetrapeptide is one of two that were listed in the Dubowchik paper that actually goes on to describe dipeptides as being optimal at that time for delivering a payload -- a drug moiety with a peptide cleavable

linker, in particular the Val Cit dipeptide that is in all of Seagen's current cleavable approved products.

Q. And, Doctor Lambert, can you tell for us you mentioned a Dubowchik paper, is that Dubowchik paper -- did that come before or after Seagen's 2004 application?

MR. CHIVVIS: Objection, Your Honor. This is outside the scope of cross.

THE COURT: Overruled.

THE WITNESS: It came before.

Q. (BY MR. RATLIFF) Now, let's bring up PDX 3.29. This is one of Doctor Bertozzi's slides.

Now, Doctor Lambert, do you recall testifying yesterday about a page from Doctor Kline's laboratory notebook that purportedly demonstrates that she made GSVQ, a tetrapeptide?

A. I do recall that.

Q. Now, let's turn to DX 1, which is the patent-in-suit, and turn our attention to column 68. And let's look at lines 8 through 9.

And, Doctor Lambert, do you see the GSVG tetrapeptide here?

A. Yes. The glycine serene valine glutamine in the one-letter code is GSVQ.

Q. And do you see that sequence is in the patent?

A. I do see that it's in the patent.

Q. And is that sequence a G/F-only tetrapeptide?

A. No, it is not.
Q. Does Seagen's patent provide any example of an ADC made using this tetrapeptide?
A. No, it does not.
Q. And is there any teaching in Seagen's patent showing a modification of this tetrapeptide to be used in an ADC as Doctor Bertozzi suggests?
A. No, there is not.
Q. Now, Doctor Lambert, let's bring up your slide 96.
And, Doctor Lambert, do you recall yesterday that Seagen's counsel asked you whether you agreed that you could have made G/F-only tetrapeptides very quickly in the lab?
A. I do recall him asking that.
Q. And do you recall that you answered you could if you knew that you had to make them?
A. I do recall my answer, yes.
Q. And can you explain to us what you meant by that response?
A. Yes, because from the instructions in the patent, if one knew one had to make a tetrapeptide, there are 83 possible building blocks to make that tetrapeptide, and you would end up with 147 million alternatives.
So there are no blazemarks, as was the term used, to guide you to decide that a tetrapeptide containing glycine and phenylalanine only were the ones to make and try.

Q. Thank you, Doctor.

Now let's bring up your slide 41.

Doctor, do any of the questions or your answers on cross-examination cause you to change your opinion that Enhertu does not infringe Seagen's patent?

A. Yes.

Q. Let me ask the question again.

A. Okay.

Q. Doctor, do any of the questions or your answers on cross-examination cause you to change your opinion that Enhertu does not infringe Seagen's patent?

A. Sorry. I was confused by the double negative. No.

Q. And do any of the questions or answers on cross-examination cause you to change your opinion that Seagen's patent claims are invalid?

A. No.

Q. Now, let's highlight this first bullet.

Now, on this first issue on your slide, if the jury agrees with your analysis that Seagen's patent is really about auristatin drugs, what finding do you believe the jury should reach?

A. That the patent is invalid because the claim is not restricted to auristatin drugs.

Q. Now, let's highlight the second bullet on your slide.

Now, on this second issue, if the jury agrees with your

analysis that Seagen's patent is really about auristatin drugs and does not teach how to make G/F-only tetrapeptide ADCs with any and all possible drugs, what finding do you believe the jury should reach?

A. I believe the jury should reach the finding that the patent is invalid.

Q. Now, let's highlight the third bullet.

On this third issue on your slide, which says, "lacks priority, so it is anticipated," can you tell us whether our U.S. patent system seeks to reward those who conceive of and possess the invention first?

A. Yes, it does.

Q. And based on all of the evidence presented to the jury, which party in this lawsuit came up with a G/F-only tetrapeptide ADC first?

A. Daiichi Sankyo.

Q. And based on the testimony of Doctor Senter and the other Seagen scientists presented to the jury, which party in this lawsuit came up with a G/F-only targeted ADC first?

A. Daiichi Sankyo were the first to do that anywhere.

Q. Now -- and if the jury agrees with your analysis of those facts, what finding do you believe the jury should reach?

A. That the patent is invalid.

Q. Now, Doctor, based upon all of your analysis and what has been presented to the jury, do you believe that Seagen's 2019

filed patent actually claims what the named inventors regarded as their invention?

A. I can only go by what's in the 200 pages of the disclosure, and what is new in all of those 200 pages were monomethylvaline compounds. So my opinion is based on the reading of all of the -- the whole document, and I would say that what they invented was monomethylvaline compounds.

Q. And, Doctor Lambert, based upon all of information that you have heard, do you know whether or not the Patent Office heard all the information presented here in these few days?

A. I can't answer if they heard all of the information presented in these few days.

MR. RATLIFF: I pass the witness, Your Honor.

THE COURT: All right. Is there additional cross-examination by the Plaintiff?

MR. CHIVVIS: Yes, Your Honor. Just a few questions.

THE COURT: All right. Let's proceed with additional cross-examination by the Plaintiff.

MR. CHIVVIS: Thank you, Your Honor.

RECROSS EXAMINATION

BY MR. CHIVVIS:

Q. Doctor, I'd like to start with the demonstrative that we looked at yesterday. You recognize what I've marked as PDX 3.55A?

A. I do recognize it.
Q. And this is the demonstrative where we walked through each of the elements of claim 1 and you agreed with me that for the first one, two, three, four, five, six, seven elements, that they were all satisfied. Correct?
A. I agreed with the questions as you asked them.
Q. Which was that these limitations of the claim are each met by Enhertu. Correct?
A. As you asked the questions, the answer was yes.
Q. And we circled two aspects of the very last element--intracellularly cleaved and free drug. Right?
A. We did.
Q. And we went over FDA documents that showed that those terms were used by Daiichi Sankyo in explaining what Enhertu is and what it does to the FDA. Right?
A. Yes.
Q. Do you agree with me that for purposes of infringement, the issue is whether each one of these limitations is met, and if all the limitations of claim 1 are met, then claim 1 is infringed and the patent is, therefore, infringed? Correct?
A. If all the limitations of claim 1 are met, the patent is infringed.
Q. And, Doctor, that's irrespective of your validity arguments about whether certain items were proprietary to Seagen or known or established in the earlier disclosure.

Correct? The issue of infringement is separate from validity. Right?

A. It is.

Q. So all those red X marks that opposing counsel was putting through the slide did not have to do with infringement. Correct?

A. I'm not -- I think I disagree with that assertion, but my --

Q. Doctor Lambert, is it your position that whether an item is confidential information to Seagen has to bear on whether there's infringement of the antibody limitation?

A. That's not what I said.

Q. Okay. So when counsel was asking you with each of these elements whether it was proprietary to Seagen, that had no -- that has no bearing on the issue of infringement in this case, does it?

A. He was asking questions in a different way than you put them, and there the answers were that the claims were not met.

Q. I'm going to ask you just straight. Let's put aside the way counsel asked you. Whether or not any of these elements in your view are proprietary to Seagen or not has no bearing on infringement in this case. Isn't that true?

A. Yes.

Q. Doctor, I'd like to turn to -- actually before I turn to this slide, Doctor, in your testimony this morning, I think

you were trying to correct an issue that arose yesterday with respect to Doctor Kline's laboratory notebooks.

Doctor, do you recall analyzing that GSVQ sequence from Doctor Kline's notebooks?

A. I recall the slide that had it on, yes.

Q. And yesterday you targeted that Doctor Kline's tetrapeptides didn't make it into the '039 Patent. Isn't that true?

A. I may have said that, but I was clearly wrong.

Q. Because, in fact, she does have her tetrapeptide from her laboratory notebook right in the '039 Patent. Right?

A. That's true. But there's no evidence that an ADC was made with it.

Q. Doctor, you agree with me that Doctor Kline's tetrapeptide from her laboratory notebook appears in the '039 Patent. Right?

A. Yes, plainly does.

Q. And you agree with me that Doctor Kline's tetrapeptide appears in the 2004 original application that was filed.

A. Yes.

Q. Now, let's go to slide 3.28 of Doctor Bertozzi.

You testified that none of the information on this slide made it into the '039 Patent, but that's not true either, is it?

A. Well, they do reproduce the Val Cit at the bottom.

Q. And it's more than just that, isn't it?
A. There is the phe lys, the two dipeptides that were in the prior art discovered by Bristol Myers Squibb.
Q. And it's more than that, isn't it?
A. I'm not sure about that.
Q. You just don't know?
A. Without looking at -- I'm pretty sure they're not there, but I would have to look at this list side by side with the '039 Patent again.
Q. And you didn't prepare or conduct an extensive analysis of every single one of these marching through to see whether they were in the '039 Patent, did you?
A. I did as thorough analysis as I could. And apart from the two dipeptides you point out that were in the prior art already even before the 2004 filing, I'm pretty sure that none of these appear as dipeptides in the patent.
Q. So let's be clear. The only ones you agree are in the '039 Patent are Val Cit?
A. That's Val Cit.
Q. And which other one?
A. You go up one, two, three -- four up from the bottom.
Q. The h phe lys?
A. I'm not sure what h stands for in this context.
Q. Well, isn't that h important? Isn't that different than phe lys without the h?

A. I don't know what the h stands for.
Q. You are an expert in this field, aren't you?
A. I have never seen phe with a small h in front of it.
Q. All right. Well, I'd like to circle another one here as well. What about Ava? Do you know what Ava is?
MR. CHIVVIS: Mr. Lee, your notations are better than mine.
Q. (BY MR. CHIVVIS) Do you know what Ava is?
A. No. I can guess, but I don't know.
Q. What's your guess?
MR. RATLIFF: Objection, calls for speculation.
MR. CHIVVIS: He is an expert.
THE COURT: He is an expert. This is his opinion. He's not speculating about anybody else. I'll overrule the objection.
THE WITNESS: Ava, A-V-A, to my knowledge is not an approved -- is not a regular amino acid, for example, like gly, for glycine. So I don't know what Doctor Kline means by that.
Q. (BY MR. CHIVVIS) Well, what is it in your view? How have you heard it referred to?
A. I don't know because, I mean, I can assume that it's -- if V is Val and A is Ala, it may be that, but I don't know.
Q. All right. Let's look at the '039 Patent and see if the

research from that Research Day presentation that you said wasn't in the '039 Patent is, in fact, in the '039 patent.

MR. CHIVVIS: Mr. Lee, could you turn -- we've got PX 001 up. That's the '039 Patent.

Can you turn to column 68? I think that's page 81 of the PDF, Mr. Lee, and let's look at the top paragraph here on column 68.

Q. (BY MR. CHIVVIS) Now, we talked about h phe lys. Right? When we were looking at Doctor Kline's presentation, the research you said wasn't in the '039 Patent?

A. You did.

Q. You see this call-out here, homo phenylalanine lysine?

A. I do.

Q. Do you think that's h phe lys?

A. I would think it was likely.

Q. So that's another one from her presentation that is in the '039 Patent. Right?

A. It is.

Q. And you see this five amino valeric acid?

A. I do.

Q. Have you heard that abbreviated Ava?

A. I have not.

Q. But do you think it would be safe to assume that it could be?

A. It could be. It's not a natural amino acid which is why

I was unfamiliar with any abbreviation that it might have.
Q. It is an amino acid, though.
A. It is an amino acid. There are many non-natural amino acids as well.
Q. So assuming that amino starting with A, valeric starting with V, and then acid, stands for AVA, that's also in Doctor Kline's Research Day or science day presentation from before the patent was filed. Right?
A. I could assume that it would be.
Q. And, of course, we have the tetrapeptide. Isn't that true?
A. We have the tetrapeptide that Doctor Kline lists in her notebook.

MR. CHIVVIS: Nothing further.

THE COURT: You pass the witness, counsel?

MR. CHIVVIS: Yes.

THE COURT: Is there additional direct?

MR. RATLIFF: No, Your Honor.

THE COURT: You may step down, Doctor Lambert.

THE WITNESS: Thank you, Your Honor.

THE COURT: You're welcome.

Is there a request that Doctor Lambert be excused?

MR. DACUS: Yes, Your Honor. May Doctor Lambert be excused?

THE COURT: Any objection?

MR. HILL: No objection, Your Honor.

THE COURT: Doctor Lambert, you're excused which means you're free to stay with us if you like; you're also free to leave.

THE WITNESS: Thank you, Your Honor.

THE COURT: You're quite welcome, sir.

Defendants, call your next witness.

MS. AINSWORTH: Your Honor, Defendants call Dr. Patrick Burke by video deposition. Doctor Burke is a director of chemistry at Seagen.

The video is 13 minutes and 34 seconds long. Two minutes and 2 seconds of that is the Plaintiff's designations. 11 minutes, 22 seconds are the Defendants designations.

And Doctor Burke will testify regarding the following exhibits: Defendant's 1, 440, and 445.

THE COURT: All right. Proceed with this witness by deposition.

MR. CHIVVIS: Your Honor, we had requested that this portion be sealed and had notified Defendants.

MS. AINSWORTH: That is correct, Your Honor.

THE COURT: All right. Then before the video deposition begins to play, I'll order that the courtroom be sealed and direct that all persons present not subject to the protective order that's been entered in this case should excuse themselves and remain outside the courtroom until the

courtroom is reopened and unsealed.

Once I'm satisfied that that sealing is complete, then we'll proceed with the witness by deposition.

(Courtroom sealed.)

(Courtroom unsealed.)

THE COURT: All right. If the witness will come forward and be sworn, please.

(Whereupon, the oath was administered by the Clerk.)

THE COURT: Please come around, have a seat at the witness stand.

NAOMI KO, M.D. M.P.H., SWORN,

testified on direct examination by Ms. Berniker as follows:

Q. Good morning, Doctor Ko.
A. Good morning.
Q. Would you please introduce yourself to the jury?
A. Sure. My name is Naomi Ko, and I am a medical oncologist. I treat breast cancer patients.
Q. Where do you live, Doctor Ko?
A. I live in a suburb outside of Boston.
Q. Do you have a family?
A. I do. I'm a proud mother to four wonderful children and two dogs.
Q. Would you please describe your education after high school but before medical school?
A. Sure. After high school, I went and attended Barnard College. And after that, I did a program called Teach for America. And from there, I ended up deciding to go to medical school.
Q. Now, Doctor, would you please describe your path to becoming a breast cancer oncologist?
A. Sure. So I matriculated at Johns Hopkins School of Medicine, and there I obtained my medical degree and public health degree. From there, I went on to do my residency training at Brigham and Women's Hospital, and I taught the patient/doctor course at Harvard Medical School.
Then I subsequently went to fellowship training at Boston Medical Center where we saw patients at the VA Hospital and at

VMC.

Q. Doctor Ko, what inspired you to become a doctor?

A. So I -- my primary caregiver when I was young was my grandmother because my parents both worked full-time. And she ended up dying of cancer when I was 13, and that left an indelible impression on me.

Q. How long have you been treating breast cancer patients?

A. I have seen cancer patients since medical school, but I have been specialized in the treatment of breast cancer since my fellowship.

Q. Over the course of your career, about how many breast cancer patients would you say you've treated?

A. I have treated probably hundreds of breast cancer patients over the course of my entire career.

Q. And where do you work now, Doctor?

A. I am at Boston Medical Center in Boston, Massachusetts, and I am at the Boston University School of Medicine.

Q. And would you tell us a little bit about the breast cancer center at the Boston Medical Center?

A. Sure. So Boston Medical Center is the safety net hospital for all of New England, which means that any patients that require care for cancer or any other medical issues are able to come there, regardless of, you know, where they live or their insurance or how much money they make. We take care of everybody.

Q. And are you co-director of that breast cancer program, Doctor?
A. Yes. So I co-direct the breast cancer program at Boston Medical Center.
Q. And what is your teaching position at Boston University School of Medicine?
A. So I'm an assistant professor. So I give lectures and teach doctors, nurses, medical students, residents, about anything in internal medicine and particularly in cancer.
Q. Doctor, what type of breast cancer patients do you treat?
A. I see them all. So I see any sub-type of breast cancer, any stage, any type.
Q. Would you say that you're familiar with the therapies that are used to treat such patients?
A. I feel that I'm -- that's my job. I need to know what all the different treatments are for breast cancer.
Q. And would you tell us a little bit about your role in teaching other doctors and nurses about breast cancer treatment?
A. Sure. So I have -- as co-director of the program, I do a lot of educational teaching. I direct the breast cancer grand rounds, which is a lecture given monthly, and I also have lecture series that we provide for the community health providers as well about cancer in general.
Q. Doctor Ko, how often do you communicate with other

doctors about the treatment of breast cancer?
A. Pretty much every day. We are inundated with a lot of information about cancer care and treatment, and we have a really great community, especially in Boston and nationwide, among breast cancer oncologists where we're in constant communication about what's happening.
Q. Have you published articles in the area of breast cancer treatment?
A. Yes. So I have at this point over 50 publications that have to do with breast cancer.
Q. Is there a particular focus to your research?
A. Yes. I am a cancer disparities researcher. So my focus is generally on the treatment of breast cancer across all populations and the challenges that we face in ensuring that all our patients get the best care possible.
Q. Have you received any awards for your work, Doctor Ko?
A. Recently I have been lucky enough to get the -- a National Humanism Award. It's the Leonard Tow Humanism in Medicine Award just a couple of weeks ago. So that's probably something I'm really proud of.
Q. Have you also received awards for your clinical care of patients?
A. Yes. So I do also have the Excellence in Clinical Care Award from our faculty practicing group. That was awarded, I believe, now two years ago.

Q. Doctor, are you being compensated for your time working on this case?
A. Yes, I am.
Q. Is your compensation dependent on the outcome of this case?
A. No, it is not.
MS. BERNIKER: At this time I offer Doctor Ko as an expert in the treatment of breast cancer and available breast cancer therapies.
THE COURT: Is there objection?
MR. HILL: No, Your Honor.
THE COURT: Without objection, the Court will recognize this witness as an expert in those designated areas and fields.
Please continue.
MS. BERNIKER: Thank you, Your Honor.
Q. (BY MS. BERNIKER) Doctor Ko, are you familiar with a product called Enhertu?
A. Yes, very familiar.
Q. And what is Enhertu used to treat, Doctor?
A. We use Enhertu for the treatment of metastatic, or stage 4, breast cancer and some gastric cancer as well.
Q. And I noticed on your slide, it says HER2+ metastatic breast cancer. Is that a particular kind of breast cancer?
A. Yes. So breast cancer has generally three major kinds,

and HER2+ breast cancer is one of them.

Q. Well, let's start with the concept of metastatic breast cancer. What is metastatic breast cancer?

A. So metastatic breast cancer is also known as stage 4 breast cancer which means the cancer has spread outside of the local regional area, so that's outside of the breast and lymph nodes, and it's deemed incurable.

Q. So what are you trying to do for the patients if it's incurable when you're treating these patients?

A. Well, I think the goal for me in treating stage 4 breast cancer patients primarily is to really know my patient. I think it's a devastating diagnosis to get, and the primary goal is for me to know who they are and what matters to them.

I think that we also focus quite a bit on making sure that their time here is as long as we can make it and as well as they can have it. And so those are my main goals.

Q. Can these patients typically be treated with surgery?

A. Typically, no, they are not. They are considered incurable.

Q. And about how many women in this country have metastatic breast cancer, Doctor Ko?

A. Approximately 150,000 women have metastatic stage 4 breast cancer.

Q. Okay. And you mentioned that Enhertu is specifically for HER2+ metastatic breast cancer. What is HER2+ metastatic

breast cancer?
A. Sure. So HER2+ is a specific sub-type where there's a receptor on the cell that is HER2 expressive, and so it has a very specific nature and personality.
Q. Now, Doctor, what kind of women get HER2+ metastatic breast cancer?
A. So all types of women can get HER2+ metastatic cancer. It's somewhat more aggressive of a sub-type. So I tend to see a general panel of pretty young women who have it.
Q. Now, going back a little bit to Enhertu, how is Enhertu had ministered to patients?
A. So it's given by an IV infusion and it's given every three weeks and it is used alone.
Q. And when you say alone, what do you mean by that?
A. It's not accompanied with other pills or medications. Generally patients feel well when they get it. Their main, you know, thing is they have to come into the infusion center once every three weeks.
Q. How does Enhertu fit in with the goal you said earlier when you're trying to treat these patients who can't be cured?
A. It's a great medication for a lot of reasons. The side effect profile is good. Women don't have to lose their hair. They generally just have to come in once every three weeks. And one of the goals that we have is to have them forget they have cancer when they're not seeing me. And so I really think

it's quite impactful for their quality of life.
Q. Now, if it doesn't cure people, what does it do for the patients, Doctor?
A. So it does an incredible job of controlling the disease. And even with Enhertu, we've seen patients have remarkable responses to their tumors where they're not only shrinking down but they're really in great control.
Q. What do you mean about controlling the tumors?
A. So with metastatic breast cancer, as I mentioned, the tumors could have spread anywhere. They could have spread to the lung, liver, or bone. And when patients get on Enhertu, those tumor masses can shrink down quite a bit, and then controlling, that means that they don't come back. They are small, they remain small, sometimes they disappear. So that's what good control looks like.
Q. What does that mean for the patient?
A. Everything. It means everything for them. They feel well. It's really amazing.
Q. Doctor, if you could explain the data that we have presented here on your next slide, and it's citing to Exhibit DX 1195.
A. Right. So when Enhertu's results came out at this time, it was remarkable, and one of the reasons that is is because when we have incurable cancer. You can see that they reported the median time of -- without the cancer progressing or

remaining in excellent control to be at 16 months.

It was really outstanding for us as physicians and for the medical community because for women who, like in my practice, who are young or are battling a cancer that we tell them is incurable, to give them back 16 months is like telling someone that they'll see their kids graduate from college or see their, you know, son quarterback their last football game or, like, do things that are so meaningful to them.

And we really thrive when we are able to provide that kind of medication.

Q. So the data that we have on this slide, those were Enhertu results that came out in December 2019. Is that right?

A. Yes, that's correct.

Q. And how do they compare to some of the other tools in the toolbox that you have to treat these patients?

A. Yes. So Enhertu is really outstanding as you can see by these results. We have lots of other great regimens as well as they're listed here, and these median times are excellent, too, but it did stand out among the other medications as being, you know, uniquely effective.

Q. So you have a few other regimens listed on this slide--the Tukysa regimen, the Nerlynx regimen, the Margenza regimen. Are there others tools that you have to treat metastatic HER2+ breast cancer patients?

A. Yes. We have a great number of wonderful treatments and medications in what I call the toolbox at times or the armamentarium where we are pulling out tools to do everything we can, kind of getting the right tool at the right time with the right fit for each patient.

Q. Well, what was the reaction in the medical community about Enhertu's effectiveness when this data was released?

A. It was astounding, nothing short of just really astounding to see these -- these numbers. Double-digit months is not something that's too common for us to see in medications.

Q. If we could take a look at your next slide, Doctor.

You have a call-out here from Exhibit DX 40. Could you describe what we're seeing here?

A. Sure. So Doctor Hurvitz is one of the lead investigators for Enhertu. And here in the highlighted area, she was quoted at the time to say, We were blown away to see the objective response rate of 61 percent and median progression-free survival of more than 16 months.

Q. And what does it mean, the objective response rate of 61 percent?

A. It means that you're seeing that patients are -- in 61 percent of the patients, that they are having a response to the medication, which is in fact quite a high number for these types of medicines.

Q. And what is median progression-free survival referring to?

A. So that was on our previous slide where it says the median time that we are seeing without the patients showing that their disease has gotten out of control.

Q. The comment that we were blown away to see this data, is that consistent with the experience that you had at the time in the community?

A. Absolutely. Absolutely. And I think that, like my colleagues as well, we were all really grateful, really super grateful.

Q. Doctor, the data we just looked at was from 2019. Was there more data published on Enhertu since then?

A. Right. So they continued to follow the patients that are on study, and so updated results keep coming out.

Q. If we could take a look at your next slide, which is citing to DX 1195 and DX 41.

Can you please tell us what's reflected here?

A. Right. So we are now, as mentioned, you know, we still are tracking patients who are on the medication. And they're doing so well, that that median time keeps getting longer and longer.

So here they keep -- the results of the trial keep getting published and the median time continues to grow, which is great.

Q. And so here the time with the updated information was 19.4 months? Is that right, Doctor?
A. Yes, that's correct.
Q. Okay. And so what does that 19.4 months mean for the patient?
A. Gosh, it means really everything. As I mentioned before, there are some really important life milestones that people are now able to meet, and I think that it makes just the world of difference.
Q. Doctor, has there been even more recent data that came out after this?
A. Yes. Yes, there have.
Q. And if you could summarize what we have on your next slide which refers to DX 43, please?
A. Sure. And so in cancers, when you see these types of results of medications, the next question becomes, well, where else can this effective medication be used and can we put it in a position that's going to help us cure more patients or make them better?

And so these are results that look at the Enhertu and it's up against this other drug, I think we mentioned here, Kadcyla, and it's showing that in that clinical trial as well, that Enhertu is showing some really strong results.
Q. Now, Doctor, I want to go back to one of your slides where you show some of the other drugs that are available or

medicines that are available to patients. Are doctors picking a single one of these to give patients or how does it work?

A. Right. So when you have an incurable disease or an incurable cancer, the goal is, as I mentioned, to keep patients alive for as long as possible and doing as well for as long as possible. And we have a lot of great tools in the toolbox.

And based on all of their side effect profiles, based on the patient characteristics of where their disease are, we will take different tools out at different times to do the absolute best job that we can to meet our patients' goals.

Q. Doctor, in your experience, do most patients get more than one of these drugs or do they only just get one of them?

A. I mean, we try to use every tool in our toolbox to the best of our ability.

Q. Doctor, what factors go into what treatments you decide to prescribe in what order?

A. I think that, first, I talk to my patient because every person has a different make-up or different comorbidity or disease or something that matters to them. So that's a first thing that I think about.

Next, I think about what strategically is one of the most effective medications. So I want to use that, but I also want to ensure that their quality of life is as great as I can keep it.

Q. Thank you.

Doctor, I want to ask about the Tukysa regimen listed on this side. Do you see that? It says 7.8 months?

A. Yep.

Q. Now, is that a drug that Seattle Genetics, Seagen, makes?

A. Yes.

Q. Is that an ADC drug, Doctor Ko?

A. No, it is not an ADC.

Q. Okay.

THE COURT: Counsel, could you slow down a little bit with your questioning?

MS. BERNIKER: Certainly. Thank you, Your Honor.

THE COURT: Thank you. Please proceed.

Q. (BY MS. BERNIKER) Okay. Doctor, what data was available about Tukysa around 2022 when Enhertu became available in the marketplace?

A. There has been a lot of great data for all of these medications. The Tukysa regimen is a regimen that was studied under the HER2 climb trial and study, which is really fantastic as well. There's been a lot of excitement about all of the new medications.

Q. Are there particular patients for which the Tukysa regimen is particularly appropriate in your experience?

A. Yes. So what's really unique and special about the Tukysa regimen and the HER2 climb study is that they included

women who had brain metastases, which means that the cancer had spread to their brain, and they were including those patients in that trial. And so it's really unique for that subset of the population.

Q. Doctor, in your experience, will most patients end up getting both Enhertu and Tukysa over the course of their treatment?

A. I think that in cancer with incurable stage 4 cancer, we want to see patients get as many effective regimens as possible. And so I think that, you know, many, if not most, of the patients will get both depending on how they do.

Q. And did you prepare a demonstrative to describe some potential sequencing of these drugs?

A. Yes.

Q. Could you explain that to us?

A. Sure. So here is a potential treatment sequence, a journey, that could occur for any patient. On the top, you'll see a regimen, we call it the Cleopatra regimen. And then after patients get that regimen and should their cancer progress, one of the options could be Enhertu. And you'll see the months that we have for progression-free survival based on the trials listed.

And then say that woman -- her cancer progresses further, then we'll have other things we'll pull out or other medicines. And we can pull out, for example, the Tukysa

regimen as an option and so forth after that.

The bottom line is just another example of potentially a woman with a similar scenario. But say, for example, she has a brain metastases or a brain cancer, you know, that we want to control and we'll say, you know, let's try to Tukysa regimen first and see how well she does on that. And then if she should progress from there, we have other options and we start putting other medications like Enhertu or others out of -- out of the toolbox.

Q. Doctor, in your view, what is the relationship between Enhertu and Tukysa?

A. I'd say I'd either call them like partners or allies in this war that we have, in this battle that we're facing. They have the same goal and they're kind of used sequentially together.

Q. Doctor Ko, do you have any examples of the ways in which Enhertu has changed the lives of your patients?

A. I have so many. I mean, there have been a lot of -- I think there have been a lot of patients in my particular panel in fact that I have seen do incredibly well with Enhertu.

I just saw a patient last week who is a mother of four as well, and she was coming up against limited options, and we were able to start her on Enhertu and she has just -- she has no evidence of disease right now and feeling quite well. And it's just been really astounding, so we're really grateful.

Q. When you say she has no evidence of disease, what do you mean? Didn't you say she was a metastatic breast cancer patient?

A. Yes. So we get these scans that look at where the lesions and tumors have spread throughout the body. And most recently, we got a scan and actually what ended up happening was there was one spot that sort of lit up. And in talking with our, you know, entire team of doctors and nurses, we opted to have her go to surgery, which I know I just said it's not that common, but in some unique cases we've sort of decided, well, she's just got this one spot, would it be amenable to just cutting that out and see how she does.

So we did do that, and right now she has -- her scans look clean. So you can see where her former masses had been, but nothing's lighting up right now, which means that the tumors are either quiet or controlled or have died off or something, and we're just really thrilled for that.

Q. And how long has she been on Enhertu, Doctor Ko?

MR. HILL: Your Honor, respectfully, I'm going to object to the relevance of these questions.

MS. BERNIKER: This was actually my last question, Your Honor.

THE COURT: Ask your last question.

MS. BERNIKER: Thank you, Your Honor.

Q. (BY MS. BERNIKER) How long has the patient been on

Enhertu, Doctor Ko?

A. I think she's been on it for at least 14 months at this points.

Q. Thank you.

MS. BERNIKER: I pass the witness.

THE COURT: Cross-examination.

MR. HILL: Thank you, Your Honor.

CROSS EXAMINATION

BY MR. HILL:

Q. Good morning, Doctor Ko.

A. Good morning.

Q. My name is Wesley Hill. I'm one of the lawyers representing Seagen. It's nice to meet you.

A. Nice to meet you.

Q. I appreciate you being here, and I want to tell you first, off the bat, ask you if it's okay if I thank you for your service to your community, to those patients that are in need that you treat.

A. Thanks.

Q. Now, Doctor Ko, have you been here for other portions of the trial this week?

A. I have.

Q. Which portions? Were you here yesterday? How long have you been here?

A. I flew in on Monday night, and then I was here for a

portion of Tuesday and yesterday.
Q. Okay. So did you see Doctor Senter describe his research and work on a flexible peptide cleaver linker for building ADCs that resulted in Seagen's 2004 patent application?
A. No. I believe I did not see that.
Q. All right. And so did you hear any of the recitation by Doctor Senter or Doctor Bertozzi about the collaboration efforts between Seagen and DSC for nine years?
A. I believe if they were on Monday, then I did not see that.
Q. Okay. Well, how about maybe yesterday? Were you here to see any of Doctor Bertozzi's testimony where she tracked Seagen's technical information for building ADCs from the notebooks of the Daiichi scientists to the development of Enhertu?
A. I don't believe I ever saw that yesterday. I think she was on Tuesday? I don't -- I don't remember exactly. I don't recall the details of that.
Q. Okay. Now, Doctor Ko, let me ask, I assume, based on the testimony we heard from you earlier, you don't have any opinions about infringement in this case. Right?
A. No, I do not.
Q. And have you ever seen or read the '039 Patent that's at the center of this lawsuit?
A. No, I have not.

Q. So safe to say you have no opinions to support DSC's defenses of written description or invalidity. Right?
A. I do not have any formal opinions, no.
Q. And, Doctor Ko, as part of your work in this case, did you ever speak with any DSC employees?
A. DSC again is -- can you define that?
Q. Yes, ma'am. I'm sorry. Daiichi Sankyo.
A. Oh. No, I have no conversations with them, no.
Q. I assume that's the same for AstraZeneca as well?
A. That is correct.
Q. Okay. And you've never read any of the expert reports of Doctor Lambert or Doctor Bertozzi in preparation for your testimony today?
A. No, I have not.
Q. And, Doctor Ko, do you understand this is a -- this is a case over money damages, whether DSC owes a reasonable royalty to Seagen for patent infringement based on its sales of Enhertu to date?
A. I have a very shallow understanding of the law. So I would say I don't really -- I know it has something to do with that, but I don't have a complete understanding.
Q. Are you aware of the fact or do you know that the result of this trial will have nothing to do with Enhertu being available to patients or whether Enhertu continues to be available to patients and on the market?

A. My understanding is that this won't have anything to do with the ability to obtain the medications.
Q. So irrespective of what the jury decides in this case, Enhertu is an available treatment and will continue to be an available treatment. Right?
A. I hope so.
Q. And are you aware of the fact that the patent that we're here talking about in this case, the '039 Patent, in fact it expires sometime in 2024?
A. I don't know anything about the patent, to be honest.
Q. Now, I think -- you'll agree with me, based on your testimony, I take it, Doctor Ko, that Enhertu is -- it's a great new treatment for breast cancer. Right?
A. It's astounding, yes.
Q. And so, Doctor Ko, do you agree with me that those who laid the foundation for that great success, that successful treatment, Enhertu, should be compensated for that contribution?
A. That's a tricky question.
Q. Doctor Ko, I appreciate you answering my questions.
MR. HILL: Thank you, Your Honor. Pass the witness.
THE COURT: All right. Is there redirect?
MS. BERNIKER: No, Your Honor.
THE COURT: Okay. You may step down, Doctor Ko.
Is there any reason Doctor Ko should not be excused?

MR. HILL: No, Your Honor.

MR. DACUS: We agree, Your Honor.

THE COURT: Doctor Ko, you're excused. That means you're free to leave and you're free to stay. It's up to you. Thank you.

Ladies and gentlemen, before we proceed any further, we're going to take a short recess. If you would, simply take your notebooks with you to the jury -- excuse me, leave them in your chairs. There's no need to take them to the jury room. This will be short.

Please follow all my instructions about your conduct, including, of course, as you would expect me to say, don't discuss the case with each other, and we'll be back in here shortly to continue.

The jury's excused for recess.

(Whereupon, the jury left the courtroom.)

THE COURT: The Court stands in recess.

(Brief recess.)

THE COURT: Be seated, please.

Defendants, are you prepared to go forward with your case in chief?

MS. AINSWORTH: Yes, Your Honor. We have three depositions coming up next. We conferred with Plaintiff's counsel. They do not need to be sealed.

THE COURT: All right.

MS. AINSWORTH: And with the Court's indulgence before the jury comes in, if I could tender the deposition excerpts that were the subject of the proffer earlier.

THE COURT: You may approach and deliver those to the Courtroom Deputy.

MS. AINSWORTH: Thank you, Your Honor.

THE COURT: Is there anything else we need to take up before I bring in the jury?

MR. HILL: Your Honor, while we have the jury out, I'll go ahead and approach and hand the Court a copy of Doctor Bertozzi's expert reports. It's what we'll be sending with her to the stand when she offers her rebuttal testimony. I'd prefer to do it now than --

THE COURT: That's fine.

All right. Let's bring in the jury, please.

(Whereupon, the jury entered the courtroom.)

THE COURT: Please be seated, ladies and gentlemen.

Defendants, call your next witness.

MS. AINSWORTH: Your Honor, Defendants call Dr. Brian Toki, who's the principal medical science liaison at Seagen and one of the named inventors on the '039 Patent, by video deposition which will be 9 minutes and 56 seconds. Four minutes and 41 seconds are Defendants' designations. Five minutes, 15 seconds are Plaintiff's designations.

And Doctor Toki will testify regarding Defendants'

Exhibit 1.

THE COURT: Proceed with this witness by deposition.

BRIAN TOKI, PhD., BY SWORN VIDEO DEPOSITION,

Q. And, Doctor Toki, are you currently employed by Seattle Genetics?

A. Yes.

Q. And your first job after your Ph.D. was at Seattle Genetics as a chemist. Is that right?

A. Yes, as a post doctoral.

Q. And that started in 1999?

A. Correct.

Q. And you worked at Seagen for, it looks like, about 12 years as a chemist. Is that right?

A. Yes, that sounds right.

Q. And so when you're developing an ADC, you want to develop an ADC that can successfully with used to treat a disease. Right?

A. Yes, I would think so.

Q. And do you know if Seagen -- or -- so the maleimidocaproyl group was already in use to conjugate drugs to antibodies, at least as early as 1993. Is that right?

A. I don't know the year, but that sounds reasonable, yes.

Q. Did you see any documents reflecting a tetrapeptide linker comprising only glycine and phenylalanine in a drug linker in an ADC prior to the first time you saw trastuzumab

deruxtecan?
A. And that includes the patent? Well, certainly there's a patent that -- a Seagen patent -- well, where I'm an inventor that discusses tetrapeptide sequences, and if you look at the possibilities of tetrapeptides, something like a glycine-glycine phenylalanine-glycine would fall into that category.
Q. Do you recognize this document?
A. Yeah, a lot of this document looks familiar.
Q. On the first page of the document in the top right corner, it has a patent number, 10,808,039. Do you see that?
A. Yes.
Q. So earlier when you testified that you had worked on an antibody -- when you had worked on a drug linker for an antibody-drug conjugate falling within the scope of these claims, what did you mean by that?
A. Well, again, I worked on pieces of the drug linker, whether it was on a spacer unit or various drugs or so on --
Q. So what --
A. -- and various peptide sequences.
Q. But those peptide sequences did not include a tetrapeptide composed only of glycine and phenylalanine residues. Correct?
A. I -- I don't recall any.
Q. So just to ask the question again, you never worked on a

drug linker that would have fallen within the scope of these claims which require a tetrapeptide composed of only glycine and phenylalanine residues. Right?

A. I -- I don't recall.

Q. So, Doctor Toki, what do you understand to have invented with respect to spacers and drug units in connection with this claim?

A. Well, the -- I mean, this teaches you or teaches the scientists, the chemists, that a variety of amino acids, whether they are di, tri, tetra, and beyond, can be suitable cleavable link systems; some with spacers, some without spacers --

Q. And --

A. -- from a variety of drug types, whether it's antimitotic or topoisomerase or a DNA-damaging agent.

Q. What disclosure in the patent directs a scientist to tetrapeptides in particular composed of only glycine and phenylalanine residues?

A. Well, if you go back to column 63, line 16, or whatever starts discussing about the linker unit and the various possibilities that one could use, and within that you would be able to find something like where only phenylalanines and glycines are used would fall into that on how you assign the R groups.

Q. You testified earlier that you are not aware of any

linker disclosed in the patent that contains a tetrapeptide composed only of glycine and phenylalanine residues. Right?

A. Correct.

Q. And you also testified earlier that the first time that you saw an ADC with a linker with a tetrapeptide composed only of glycine and phenylalanine residues was in trastuzumab deruxtecan. Right?

A. Yeah, I can't think of any earlier examples.

Q. So what's new in your patent is MMAE and MMAF. Right? In ADCs?

A. Yes. And, again, the chemistry that's associated for making that.

Q. This line in your patent doesn't direct a scientist reading your patent to refer to this paper for information about synthesis. Right?

A. As it is written in that paragraph, yes.

Q. Right, yes, you agree with me? It's referring a mechanism of drug release. Right?

A. Yes, in this paragraph.

Q. Had you done work prior to the filing of the patent November 5th, 2004, on drugs in the camptothecin class to see whether they'd be useful as drugs that could be conjugated in ADCs with peptide linkers that would intracellularly cleave?

A. Yes, I had done some work with this class, including camptothecin itself; 9 amino-camptothecin; irinotecan, which I

think is an adduct of SN-38 that I worked with.
Q. Could you please describe that work?
A. It involved a few different things. It was of making peptide linkers like, for example, directly connected to the 9 amino-camptothecin. With both camptothecin and -- and the irinotecan, there were things like carbonates made, ether linkages made similar to what was demonstrated in -- in the JOC paper 2002, I think.
Q. So if you can recall, what drugs come to mind that Seattle Genetics was working with for use in intracellularly cleavable ADC -- ADCs prior to November 5th, 2004?
A. Well, in a broad sense, certainly antimitotic agents like the auristatins, topoisomerase inhibitors like doxorubicin, like some of the various camptothecins, SN 38, 9 amino-camptothecin. Also with minor group binders, we were working on that at that time and probably others that I would have to think about. But certainly a number of classes of molecules we were looking at.
Q. Right. Are you aware of anywhere else in the patent that it states that this list of chemotherapeutic agents in columns 31, 32, and 33 are useful as the drug moieties in an ADC?
A. Well, I would think someone skilled reading this could pick out some of these things and say, yes, these could -- could make ADCs that could be cleaved inside of cells.

Q. Doctor Toki, at the time you filed your patent application, did you consider yourself in possession of ADCs containing every single drug listed here in columns 31, 32, and 33?

A. No.

THE COURT: Does that complete this witness by deposition?

MS. AINSWORTH: It does, Your Honor.

THE COURT: Call your next witness, please.

MS. AINSWORTH: Your Honor, Defendants call Dr. Svetlana Doronina, who is a senior principal scientist at Seagen and one of the named inventors on the '039 Patent.

The video is 16 minutes and 49 seconds. Thirteen minutes and 5 seconds are Defendants' designations. Three minutes and 44 seconds are Plaintiff's designations.

And Doctor Doronina will testify regarding Defendants' Exhibit 466 and 475.

THE COURT: Please proceed with this witness by deposition.

SVETLANA DORONINA, PhD., BY SWORN VIDEO DEPOSITION,

MR. CHIVVIS: And I also wanted to note on the record that the witness is testifying here today in English. English is not her first language. She feels comfortable, but it will be important to talk slowly. And I'm sure she'll speak up if she has any confusion about the questions you're

asking.
Q. Doctor Doronina, is what your counsel just explained true?
A. Yes.
Q. Okay. And when you work -- you work at Seagen. Right?
A. Currently, yes.
Q. And so am I right in understanding then that in 2000, you moved to Seagen?
A. Yes. That's correct.
Q. I'm right, though, that other groups had already reported the conjugation in ADCs of drugs via MC groups. Right?
A. It's been known in the literature, yes.
Q. So when you said, I likely became aware of DSC's camptothecin conjugates in 2016, what you meant is I likely became aware of the structure of the DS-8201 in early 2016.
A. Yes.
Q. Doronina, did anyone at Seagen ever make and test an ADC containing a glycine phenylalanine tetrapeptide linker?
A. Not to my knowledge.
Q. Before you became aware of the structure of DS-8201 --
A. Yeah.
Q. -- had you ever envisioned an ADC using a tetrapeptide linker containing only glycine and phenylalanine?
A. Yes. It's in our invention that's been pub -- been filed in 2004. The -- depicts the tetrapeptide linkers for the ADC

technology, and it -- and in the description of the amino acids, that lists all amino acids, including the glycine and phenylalanine.

Q. Is there anything in the patent that points you to glycine and phenylalanine only containing tetrapeptide?

A. It could if skilled in the art.

Q. How so?

A. There is enough disclosure there.

Q. So, Doctor Doronina, I will now hand the court reporter what will be Exhibit 4. And do you see that it says application No. 60/518,534?

A. Yes.

Q. And it says November 6, 2003. Do you see that?

A. Yes.

Q. So sitting here today, you have no knowledge of why those particular peptide unit sequences were exemplified in the patent?

A. That's some of the exemplary sequences that could be used, but when we use just -- when we just list 39 amino acids, right, it's like -- we just counted them -- 36, whatever. But, anyway, so it's -- as we discussed, it's a significant number of amino acids.

So people typically, in the patent, in my understanding, propose few examples that would give people -- other people who read the patent some idea where to start their work should

they be interested in using this invention for their own purposes.

Q. So kind of give them a --

A. Head start to use of this invention for their purposes --

Q. Or like a --

A. -- should they use --

Q. A research plan, sort of?

A. A research plan, yes.

Q. It doesn't direct the skilled person, though, to use tetrapeptides containing only glycine and phenylalanine. Right?

A. I actually not agree with what you just said. I think that there is enough disclosure on this page that any skilled in the art person would quickly arrive to the very limited number of tetrapeptide sequences to use in their work, which one of them would be gly-gly-phe-gly.

Q. Doctor Doronina, when was the first time you thought of that rationale?

A. I don't remember the exact date when I thought of this rationale. I can say it was not at the time this -- at the time we --

Q. It wasn't in 2003?

A. No.

Q. And it wasn't in 2004?

A. No.

Q. Okay. Was it within the last week?
A. No.
Q. Within the last year?
A. Probably.
Q. Okay. You walked me through in that answer several steps in logic to go from the two tetrapeptides listed on page 25 --
A. Correct.
Q. And if you are concerned with the hydrophobicity of your drug?
A. Then as I suggested, you would replace R21 with gly, which would give you gly-gly-phe-gly.
Q. Okay.
A. And after, you can add whatever you consider reasonable and --
Q. And what else -- oh, I'm sorry.
A. -- whatever you would like to try else. Like some of the exemplifications here, like, with the -- if you want to deal with the protected amino acids, you can add lysine in the P1 because there are a lot of examples with lysine in the formula 8, for example.
Q. Formula 8 gives a lot of examples with lysine in P1.
A. Right. But it's up to you. I think you can limit it. If -- I think what I'm trying to say is that depending of how much time and effort the skilled enough person would want to spend testing different peptides, the person can add as many

as it can find reasonable based on this exemplification.

However, if they want to limit their experimentation, the most rational way would be follow what I described to you. And that would lead to, I believe, four or five peptides. I can count again, but we already proven we're so bad in math that...

Q. Let's do that, please. So what is the list?

A. We're going from the N-terminus to C-terminus. From R20 to R21 to R23 to R -- no, 21, 22, and 23.

Q. Right. I'm with you.

A. So gly-phe-leu-gly, gly-phe-phe-gly, gly-gly-leu-gly, gly-gly-phe-gly.

Q. So that's four.

A. Okay.

Q. You mentioned you --

A. And you can add the second one which is exemplified which will be ala-leu-ala-leu.

Q. And --

A. The rest, it's up to you. If you want to do more work, it's up to you.

Q. I see. So this is --

A. This is what I think skilled in the art person who decided to develop -- decided to use this invention for the tetrapeptide linker would start doing after thinking and analyzing what's disclosed in this page.

Q. What, if any, tetrapeptides does this disclosure direct the skilled person away from?
A. What's written on this page doesn't necessarily direct away from anything.
Q. And you explained to me that the disclosure on, for instance, pages 24 and 25 and 26 of this application direct the skilled person to use a smaller subgenus of the five sequences we've been discussing.
A. Not exactly. I think I said that I think the word 'direct' is very strong because there is no directions here, explicit directions.
Q. So there are no blazemarks pointing the skilled person to that particular subgenus?
A. There is enough information on this page that would lead or point -- let's see -- point skilled in the art person in a direction of -- now I use the word direction myself -- point in -- towards those sequences.
Q. Sorry. I think we spoke over each other. In 2003 and 2004, you didn't think I should use these five sequences in my ADCs.
A. I did not specifically felt that I should not use those sequences. I just did not think about the subject. My priority at the time were not to make tetrapeptide ADCs, so I did not really thought about what sequences I would do at this time.

Q. Okay. Then I'm confused why the skilled person would -- why you believe this disclosure points the skilled person to vary the top peptide sequence but not the bottom one, preferentially.
A. I believe that people read from top down to bottom. So the first thing the person would see is the top sequence, and it's logical to suppose that that would be the first one they would consider, considering that this invention does not point directly -- or doesn't -- that's a word that you actually used -- doesn't point in particular way to one or another, other than one is on top and the other is on the bottom. People read from top down to bottom.
Q. Okay. So part of the basis for your understanding that the disclosure on page 25 points the skilled person to the set of five peptides we've been discussing is that the gly-phe-leu-gly example appears above the second example.
A. I think it very well might be the case.
Q. And where did you receive that Ph.D.?
A. In the University of Louis Pasteur in Strasbourg, France.
Q. Ah, okay. And did you receive any degrees before that?
A. Master's degree from the Novosibirsk State University in Russia.
Q. And you don't likewise recall any documents showing that anyone at Seagen before, say, 2005, ever made a tetrapeptide linker containing only glycine and phenylalanine. Right?

A. I personally have not seen any documents.
Q. Okay. And did you review documents in preparation for your deposition today?
A. Yes.
Q. And/or did any of those documents reflect that anyone at Seagen had made a tetrapeptide linker for an ADC containing only glycine and phenylalanine?
A. I have not seen any.
Q. Are the claims of the '039 Patent the first time you've seen described a genus of tetrapeptide linkers that's limited to glycine or phenylalanine?
A. To the best of my understanding, yes.
Q. What drugs did you envision would be used with your -- with the peptide linkers you described in 2003 and 2004?
A. You're talking about me personally or in broader sense?
Q. You and the other inventors.
A. Okay. So co-inventors, okay. So in this time frame we were using and considering to use of these linkers -- peptide linkers for a number of different drug included minor-groove binder, camptothecins doxorubicin analogs, the kinase inhibitors, HDA inhibitors, and I might be missing some others.
Q. Did you review any other documents without your attorney's direction?

A. Yes.
Q. And what documents are those?
A. My own slides, old slides, old papers, some notebook. My own. My own old presentations, old -- some old papers, and some old notebooks.
Q. Have we looked at any of those documents today that you --
A. Yeah.
Q. -- have? Are there others you looked at that we haven't reviewed together today?
A. Yes.
Q. Okay. When were those documents created?
A. They varied through 20 years.
Q. Over the course of 20 years.
A. Yes.
Q. And do those documents show any tetrapeptide drug linkers?
A. I have not made any tetrapeptide drug linkers, so they can't show it. It's my own documents.
Q. And so, Doctor Doronina, I'll ask you to first hand this document to the court reporter so she can mark it as an exhibit.
Okay. And, Doctor Doronina, this is one of the several documents you looked at on your own in preparation for this deposition. Right?

A. Yes.
Q. Okay. And you've explained to me before that you believe this is a document reflecting your best effort to identify all the drug compounds and drug linker compounds Toni Beth Kline made while at Seagen.
A. Yes. That's a summary of all compounds I was able to identify at the time.
Q. Okay. And at what time did you prepare this document?
A. Few years after Toni left.
Q. Are there any tetrapeptide linkers shown on this page?
A. Yes.
Q. And which compound number is that?
A. 1379.
Q. Okay. And 1379 is the only tetrapeptide linker shown on this page. Right?
A. Yes.
Q. Am I right that compound 1379 contains a glycine-serene-valine-glutamine --
A. Yes.
Q. -- tetrapeptide linker?
A. Yes.
Q. And by my count, we've identified one tetrapeptide linker in compound 1379. Right?
A. Yes.
Q. Okay. And so now that we've reviewed this document,

sitting here today, you're not aware of any other tetrapeptide linkers that Doctor Kline, you, Doctor Toki, or Doctor Senter made while at Seagen. Right?

A. I can only speak that I'm not aware that I made, and I'm not aware that Toni has made. I cannot speak for Brian and Peter.

Q. Sitting here today, do you know that they have made compounds with tetrapeptide linkers?

A. I don't know.

Q. Okay. Daiichi Sankyo Company was the first company to describe an ADC using a GGFG linker. Right?

A. I mean, in the broad term of -- in the broad terms, it's been described it -- antibody antibody-drug conjugate is -- linker is encompassed in the invention disclosure of 2003 where the tetrapeptide linker is described in the both glycine and phenylalanine are listed as amino acids that are suitable for this linker.

THE COURT: Does that complete this witness by deposition?

MS. AINSWORTH: It does, Your Honor.

THE COURT: Call your next witness, please.

MS. AINSWORTH: Your Honor, Defendants call Dr. Toni Kline, who previously worked at Seagen from 2001 to 2005, and is one of the named inventors on the '039 Patent. This video is 13 minutes and 33 seconds long. Nine minutes and 40

seconds -- 46 seconds are Defendants' designations, and 3 minutes and 47 seconds are Plaintiff's designations.

And Doctor Kline will testify regarding Defendants' Exhibits 1, 533, 538, and 636.

THE COURT: All right. Proceed with this witness by video deposition.

TONI KLINE, PhD., BY SWORN VIDEO DEPOSITION,

Q. How long have you worked in the drug discovery field?

A. Since I got my Ph.D. in 1980.

Q. You're familiar with Enhertu. Right? An antibody-drug conjugate?

A. Yeah.

Q. You worked at Seagen from 2001 to 2005. Right?

A. Yes.

Q. And how do you find out if it is cleaved by that lysosomal proteolytic process intracellularly?

A. You have an assay that tells you that. You have an LC-MS assay that tells you if you put that in a cell, wait 24 hours, light the cell, spin down the protein and inject it into the LC-MS with appropriate standards, you see what you see.

Q. So until you do an assay like the one you've described, you wouldn't know whether the linker you have engineered is going to be successfully intracellularly cleaved by the enzyme.

A. In science you never -- in science you never know

anything until you assay it.
Q. Have you -- in your experience, have you tested linkers that performed well in the kind of in vitro assay we discussed that did not demonstrate intracellular cleavage in, for instance, an in vitro mouse model?
A. I don't remember. There were things where the holistic ADC underperformed, but you don't know if that's because of the linker or the payload or some combination. Again, you have to treat these things holistically. You can't say, oh, it was a linker. If it were that simple, the whole field would be a lot simpler. It's not a simple field. There are a lot of moving parts.
Q. And there's no one linker that will just work for every drug.
A. There is no one linker that will work for every drug.
Q. Let's take a look at what's been marked as Exhibit 7. Do you recognize this document?
A. Yeah. That was our attempt on Mount Adams.
Q. Your attempt on Mount Adams. What does that mean?
A. Look at the back.
Q. Fair enough. But maybe just in terms of the actual words on the page as opposed to the picture, you are saying beyond auristatin, that was sort of the search for the next payload?
A. I suppose that's what we meant.
Q. And so that's why you said on the last page you've got

this -- the next mountain to climb?
A. Uh-huh.
Q. It's to find the next --
A. Exactly.
Q. -- drug?
A. Exactly.
Q. And so you do not recall ever testing an ADC with a tetrapeptide linker.
A. I don't -- I don't remember.
Q. When was the first time you ever saw an ADC with a tetrapeptide linker?
A. I don't remember. I mean, sometime between 2002 and 2005, as -- 2001 and 2005. I don't remember the time.
Q. In the course of preparing for your deposition or at any time, do you recall reviewing a document in which an individual at Seagen made and tested an ADC containing a tetrapeptide linker?
A. No.
Q. I'm going to show you now what will be marked as Exhibit 12. And, Doctor Kline, do you recognize this document?
A. No.
Q. No, you don't. When is the last time you looked at it?
A. Oh, I've got my name on it. So I guess the last time I looked at it was December of 2004, yeah. So apparently this was something that I prepared in December of 2004.

Q. Sitting here today, do you recall what this document represents?
A. Yeah. So this must have been when I was getting interested in different peptides, different sequences, how much can we challenge the canon of Val Cit. All of this was sort of a 2004 question. And so I did some literature searching and created this, as you see here, with the rationale what do we know about these sequences? Have they been used before anywhere? Has someone published them? Okay?
So now that my memory is being refreshed, yeah, I can see that I was looking to see what do we learn from the literature about various tetrapeptides and tripeptides.
Q. Okay. And so in December of 2004, you were thinking about which tetrapeptides you should experiment with?
A. This was a -- essentially a literature search to look at interesting tetrapeptides to be explored, whether they're properties, who's used them.
Q. So sort of a research plan.
A. Yeah.
Q. But you hadn't envisaged the genus of glycine phenylalanine only containing tetrapeptides here.
A. We didn't envision limiting ourselves.
Q. And, indeed, you didn't envision experimenting with them. Right?
A. No. I mean, we wouldn't have looked into this if we

didn't feel it was worth experimenting with, too. But you, if possible, try not to limit yourself. In a chemistry exploration, you try to make as many and diverse analogs as you can possibly -- as you have the bandwidth to execute.

So we would not have restricted ourselves to just two components, two building blocks. We would have included those building blocks in a larger repertoire.

Q. And as of 2004, there was nothing in the art suggesting that you should pursue glycine phenylalanine-only tetrapeptides as ADC linkers. Right?

A. There was nothing that suggests that we should limit ourselves to anything.

Q. And there was nothing in the art that suggests glycine phenylalanine-only containing tetrapeptides were likely to be useful in ADCs.

A. There was nothing suggesting they would or would not be. This was experimental work.

Q. Okay. As of December 12th, 2004, was Seagen in possession of ADCs linked via glycine phenylalanine-only tetrapeptide linkers?

A. I can't remember.

Q. Okay. So now I'm going to hand you, Doctor Kline, what will be marked as Exhibit 13. This is United States Patent 10,808,039. You see that in the upper right corner?

A. Uh-huh.

Q. And you are listed as the -- or one of --
A. Uh-huh.
Q. -- four inventors. Right?
A. Uh-huh. Uh-huh.
Q. So is it fair to say that this and what follows in column 65, 66, and it looks like all the way through 68, is the patent's description of the amino acid unit, that W unit we saw in the claims?
A. Uh-huh. And here it's expanded to every natural amino acid that I can imagine, and it -- as well as a plethora of non-coded amino acids. So this is an appreciably expanded definition.
Q. Let me ask the question again. In this two-and-a-half-, three-column disclosure, what blazemarks are there for a tetrapeptide containing only glycine and phenylalanine?
A. It's not called out. It is encompassed within these. And if one chose to make it, one could make it using what is described here.
Q. So it doesn't -- nothing in here points you one way or the other towards or away from the gly/phe-only containing tetrapeptides.
A. I would say that's correct. Nothing points you toward it or away from it.
THE COURT: Does that complete this witness by deposition?

MS. AINSWORTH: It does, Your Honor. It does not, Your Honor. Pardon me. We have had a -- just a technical glitch and there is more.

THE COURT: All right. Let's continue with it.

Q. Sitting here today, are you aware of any example in this patent in which an ADC containing a tetrapeptide linker containing only glycine and phenylalanine is described?

A. Of the limited examples described in the patent, I'm not aware of any specifically with that structure.

Q. If someone said that this document reflected examples containing tetrapeptide linkers, would you agree or disagree with that?

A. This particular presentation was restricted to dipeptides or spacer units, x1, x2 units, of approximately the same distance as the dipeptide. It was a very limited presentation.

Q. So you would disagree with the statement that I -- I offered.

A. This presentation did not encompass tetrapeptides.

Q. What -- can you pull up, Doctor Kline, the presentation which was your Science Day presentation, dated November 18th, 2004, with the Bates No. at the end 41039?

A. Right. Science Day. 41039, yes.

Q. I'd like you to turn to page 41046. That's the ending Bates number again?

A. Okay. The table.
Q. Now, can you tell us whether, in light of this page, you had tested peptide sequence that involved only gly, only phe, or a combination of only phe and gly as a peptide linker?
A. We had gly-phe. It's the third one from the bottom.
Q. Any others that involved only glys or only phes?
A. Right. We have phe-phe, which is a couple of ones up. What else do we have? Gly-gly, which is the first one. And -- okay. And that's -- I think that's it for phenylalanines and glycines. They appear in gly-phe, phe-phe, and gly-gly.
Q. And what do the data shown on page 41046 tell a skilled artisan about whether peptide sequences involving only gly and/or phe would cleave intracellularly?
A. Certainly from these data, which gave good results into cell lines, one could infer that these were good cleavage substrates. Either phenylalanine or glycine at the P1 and P2 positions were acceptable.
Q. Earlier you were asked whether you recalled working on tetrapeptides for use in ADCs. After further review of your lab notebooks, how would you answer that question today?
A. Yes.
Q. You do recall working with tetrapeptides for use in ADCs now?
A. Yes.

Q. In your testimony -- excuse me. In your testimony you referred to work with dipeptide and tetrapeptide libraries. Would that work have supported the disclosure in the patent of the use of any of the naturally-occurring amino acids in a tetrapeptide sequence?

A. Yes. The work on dipeptide and tetrapeptide linkers that I did would have supported what went into the patent, if that's what you're asking, yes.

Q. Okay. I'd like you to go back and look at the page ending SGIEDTX00041046. Are you with me? That's the in vitro cytotoxicity values?

A. Yes.

Q. Okay. And my question is, are there any tetrapeptides shown on this page at all?

A. No.

Q. But there are no tetrapeptides --

A. No, there are no tetrapeptides at all within the scope of this presentation.

THE COURT: Does that complete this witness by deposition?

MS. AINSWORTH: It does, Your Honor.

THE COURT: All right. Defendants, call your next witness.

MR. DACUS: At this time, Your Honor, Defendants rest their liability case subject to putting on the damages

portion of the case according to the Court's procedures.

THE COURT: All right. Are the plaintiffs prepared to go forward with their rebuttal case regarding issues of liability and non-damages?

MR. HILL: Yes, Your Honor, we are.

THE COURT: Call your first rebuttal witness, please.

MR. HILL: Thank you, Your Honor.

MR. CHIVVIS: Your Honor, Plaintiffs call -- Plaintiff calls Dr. Carolyn Bertozzi.

THE COURT: All right. Doctor Bertozzi, if you'll return to the witness stand. And I remind you, you are under oath. You've already been sworn. Please return to the witness stand when convenient.

THE COURT: All right, counsel. You may proceed with your direct examination of the witness.

CAROLYN BERTOZZI, PhD., PREVIOUSLY SWORN, testified on direct examination by Mr. Chivvis as follows:

Q. Doctor Bertozzi, welcome back.

A. Thank you.

Q. Doctor, were you here for the testimony of Doctor Lambert?

A. Yes, I was.

Q. I'd like to pull up Doctor Lambert's demonstrative slide No. 96. Do you see this slide?

A. Yes, I do.
Q. Could you read the title and tell us whether you agree?
A. The title says, "No blazemarks to ADCs with G/F-only tetrapeptides in the 2004 application."
Q. Do you agree with Doctor Lambert's assertion there?
A. I disagree.
Q. Well, we'll get into some of the details here, but can you tell us at a high level why you disagree with what Doctor Lambert has asserted here?
A. I disagree because I do find such blazemarks, as they're called, which is guidance both from the patent document itself as well as from the prior art to arrive at the tetrapeptide sequences that we're discussing.
Q. Doctor, let's pull up the 2004 patent application. That's, I think, PX 73, at page 87 here.
What do we see at the top of the original 2004 patent application?
A. At the top, which is blown up here, is a description of the lengths of peptides that are suitable for making such ADCs, as well as chemical structures that illustrate examples of the identity of the amino acid building blocks used to make those peptides.
Q. And can you point us to where some of the marks, the indications are that there are elements of the tetrapeptide with gly and phe from this formula?

A. Yes. So as to the length of the tetrapeptide that is -- you can highlight that in the very first line, tetrapeptide. And then as to the identities of the amino acid building blocks, if you look below where R19 is, and then you can highlight hydrogen, that's the example of G, as well as benzyl, and that's the example of F.

Q. Doctor, let's turn a little bit further into the original 2004 disclosure.

MR. CHIVVIS: Page 89, Mr. Lee.

Q. (BY MR. CHIVVIS) What do we see at the top here, and can you tell us whether that give us any blazemarks?

A. Yes. So this structure shows an example of tetrapeptides, and that table with R20, R21, R22, and R23 are examples of amino acids that could be in this tetrapeptide.

Q. And can you discuss the first example and whether it provides directions pointing towards gly and phe tetrapeptides?

A. Yes. So the first row in that table has R20 H, that's G. R21 is benzyl, that's F. R22 isobutyl, that's an amino acid L. And then, finally, R23 is H, and that's G again.

Q. How many Gs and Fs do we have in that tetrapeptide?

A. There are three Gs and Fs in this four amino acid peptide.

Q. All right. And let's --

MR. CHIVVIS: If we could put that table on the

bottom, Mr. Lee, and show the table of tetrapeptides from the previous page right above it. Yeah, you've got -- right there. That table No. 8 on the bottom, Mr. Lee, with the structure and the list there.

If we put that on the top of the page and the list of the tetrapeptides, the next table, on the bottom of the page. And maybe shrink just a little bit so it fits together.

Thank you, Mr. Lee.

Q. (BY MR. CHIVVIS) Doctor, what can you tell us about what the combination of these two sets of examples would show to a person of ordinary skill in the art about gly and phe tetrapeptides?

A. Well, the graphic on the top is a tripeptide structure, and the amino acids as examples are shown in R20, R21, and R22.

And if you look at R20, going down the column, benzyl, which is the top entry there, that's F. And the bottom entry H, that's G.

And then going over to R21, which is the second amino acid in the tripeptide, in all three example sequences R21 is F.

Q. Doctor, just pausing on that for a moment, what's the significance of the R21 position shown here and how -- what position does that compare to in the tetrapeptide shown below?

A. The R21 position in the structure on top is the second

position from the right. We call that the P2 position. And that's important because one of those proteases, the scissors, likes to cut peptides that have a benzyl group at that P2.

So when F is P2, it tends to be easily cut. And that's the top graphic interpretation.

Q. Doctor, this idea of a P2, I think it calls, at least into my mind, a question, how do we read an amino acid sequence? Do we read it from the left to the right or from the right to the left?

A. We read it from the right to the left. So it's the opposite of the way you read words in English. So P1 would be the amino acid all the way to the right, and P2 is one to the left of that, so it's the second one from the right.

Q. So tell us in the table from the 2004 patent application marked as table No. 8 here in Roman numerals, which position is the P1 position?

A. In that top graphic, the P1 position is R22.

Q. And in the table on the bottom, which is table with Roman 9 from the 2004 patent application, which -- which position is P1 in that table?

A. Again, P1 is all the way on the right, so that's R23.

Q. All right. So if we wanted to compare the P2 position and -- and think about how proteases cleave and -- and where they like to cleave, what do you draw by comparing the tripeptides in table 8 to the tetrapeptides in table 9?

A. Well, if one looked at the tetrapeptide in structure 9, one might notice that in the first column the sequence is GFLG, where L is P2, and one might look at the tripeptide on top and notice that P2 is always F.

So one might combine those two examples and realize that additional sequences might include GGFG, where there's an F at P2 of a tetrapeptide, just as there are Fs in P2 of the tripeptide.

Q. Doctor, I feel like you might have been speaking to us a little bit as you would in a passive voice as a scientist. How would one of ordinary skill in the art take direction from what is presented in tables 8 and 9 of the 2004 patent application with respect to tetrapeptides?

A. The person of skill in the art who wanted to make tetrapeptides for their ADC would look at these sequences and understand that F at P2 would be a choice that is clearly stated in this patent specification, and they might take that knowledge and put F in P2 of their tetrapeptide.

Q. And would that point towards gly and phe-only tetrapeptides?

A. Yes, it would.

Q. Why's that?

A. Because looking at the tetrapeptide sequence with the sequence GFLG, which has three Gs -- sorry, three Gs and F and one amino acid that is not G or F, but that one amino acid

that is not G or F is in the P2 position, and that tripeptide example teaches the person of ordinary skill to put F in the P2 position.

So combining these two, a G/F tetrapeptide I think is a very clear choice to pursue.

Q. Doctor, you talked about this concept of proteases liking to cut at the P2 position and phenylalanine being a good choice there for that reason. Are there any citations in the literature that you considered as -- as you came to that opinion?

A. Yes.

Q. Doctor, I'd like to pull up Plaintiff's 505.

Doctor, what's this article?

A. This is a scientific research publication from the year 1998 where the researchers were looking at different peptide sequences and their cleavage activity with proteases.

Q. If we look at page 4, and if we magnify the paragraph on the bottom right there that begins with cathepsin B and cruzipain, is there anything from this paragraph that informs us about a peptide cleavage at the P2 position?

A. Yes. These researchers were looking at different amino acids at this P2 position and the activity of these proteases as scissors, and they state in this article that of amino acids they tested, nothing is as good as phenylalanine at that P2 position.

Q. And how would that have informed a person of ordinary skill in the art reading the 2004 Seagen patent application with respect to what would be a good choice for a tetrapeptide at the P2 position?
A. So the person of ordinary skill would have read and be aware of this relevant research publication, and they would incorporate this knowledge into their design of a tetrapeptide.
Q. And would that help them arrive at tetrapeptides with G and F-only?
A. Yes, it would.
Q. Doctor, I think you spoke about this before in your remarks last Tuesday. I'd like to pull up Plaintiff's 1014. You recognize this email?
A. Yes, I do.
Q. And if we zoom back in on the bottom there, the bottom discussion, can you remind us again who this email is from?
A. Yes. This email was sent by Daiichi Sankyo scientist Dr. Kasuya to several colleagues of his at other institutions.
Q. Was Doctor Kasuya one of the individuals that worked in the collaboration with Seagen?
A. Yes, he was.
Q. Was he one of the scientists who also worked on the development of Enhertu in DSC's internal working group?
A. Yes, he was.

Q. What does he say here, if anything, about the -- the leap from GFLG, which was in the 2004 patent application as we saw, to a tetrapeptide with G and F-only?
A. So in the text of this email, he is first telling his colleagues about the FDA-approval of Enhertu. And then he comments that in the design of Enhertu, they used a GGFG linker as a modified version of the sequence in the 2004 patent application, which was GFLG.
Q. And if we turn back to the art that would have informed one of ordinary skill back before the patent application was filed, is this type of analysis, moving from GFLG to a G or F-only tetrapeptide supported by the literature?
A. Yes, that was supported by the literature.
MR. CHIVVIS: If we could look at PX 156, Mr. Lee.
Q. (BY MR. CHIVVIS) What's this article?
A. This is a research article from 1997 on the study of polymer peptide-drug conjugates.
Q. And, Doctor, does this article speak to GFLG and consideration of G or F-only tetrapeptides?
A. Yes, it does.
MR. CHIVVIS: If we could turn to page 4, Mr. Lee. And I think we're going to be zooming in here on -- I think it's the -- it's a little bit hard for me to read, but I think it's the left-hand side. Let me see here. Yes, right there, Mr. Lee.

Q. (BY MR. CHIVVIS) So how does the discussion here, Doctor Bertozzi, inform the analysis of whether GFLG would lead one to consider G or F-only tetrapeptides?

A. In this section, the authors discuss a peptide drug linker conjugate with GFLG, and that can be highlighted on the fifth line down.

Thank you.

And then other tetrapeptide sequences are explored, including those that are all G as well as G/F-only.

Q. And if we look back to the abstract, in addition to the all G tetrapeptide, what other tetrapeptides were considered moving from the starting point of GFLG?

A. Yes. Going back to the abstract --

MR. CHIVVIS: Mr. Lee, if we could show the abstract of the article for everyone. The very beginning the first page on it. Zoom in on it.

THE WITNESS: Thank you.

On the third line the authors summarized their work on all G and F tetrapeptides, including GGFG and GFGG.

Q. (BY MR. CHIVVIS) Doctor, what's your opinion on whether the 2004 patent application provides blazemarks to a skilled person to make tetrapeptides with G and F only?

A. It's my opinion that there are clear blazemarks in the patent application combined with the prior art, the research that was already out there from years earlier in some cases,

and that information gave very clear blazemarks for making G/F-only tetrapeptides.

Q. And, Doctor, is your analysis the same if we're looking at the disclosure of the '039 Patent?

A. Yes, my analysis is the same.

Q. And why is that?

A. Because the specifications of the '039 Patent are the same as the specifications in the 2004 patent application.

Q. I'd like to pull up another one of Doctor Lambert's slides. This one is -- I'm trying to remember the slide number here. The one titled, Many Drug Types were not Attachable to Make ADCs.

MR. CHIVVIS: That's DDX 60. Doctor Lambert's slide No. 60.

Q. (BY MR. CHIVVIS) Were you here for Doctor Lambert's presentation on this slide?

A. Yes, I was.

Q. And let's walk through this. Do you agree that non-conjugatable drugs are non-conjugatable?

A. Yes, by definition that would be true.

Q. All right. But let's focus on the other ones that he's listed here. Tertiary amine. Were drugs with a tertiary amine conjugatable as of 2004?

A. Yes. If a person of skill wanted to conjugate tertiary amine drugs, they could find a way to do that in 2004.

Q. And is there an example in the 2004 patent application of doing just that?
A. The 2004 patent application lists a variety of drugs.
Q. Doctor, did the inventors, in working with auristatins, achieve a way to conjugate through a tertiary amine?
A. Yes, they did.
Q. Is that work disclosed in the 2004 patent application?
A. Yes, it is.
Q. Let's move to thiols. Would that have been technology -- conjugation technology, drug conjugation technology, that was available as of 2004?
A. Yes.
Q. Could you please explain?
A. The chemistry to conjugate thiol-containing drugs to linkers for ADCs is classic chemistry that predates 2004 by decades.
Q. Doctor, were there even examples of drugs that had been used in ADCs with thiol groups that had been conjugated to antibodies as of 2004?
A. Yes.
Q. Could you give us an example?
A. Doctor Lambert showed an example from his company ImmunoGen from 1992.
Q. How long before the 2004 patent application is that?
A. That's 12 years before 2004.

Q. And if -- let's just pause on this slide for a second. I want to move to another exhibit.

MR. CHIVVIS: If we could pull up PX 1. And this is the '039 Patent. I'd like to move to column No. 3 of the '039 Patent. And if we scroll down a bit here, right at line 37, if you could zoom in around that area, Mr. Lee.

Q. (BY MR. CHIVVIS) Does the '039 patent -- let me see. Excuse me. I think it must be line -- oh, it's listed as line 37 and again at line 43.

Does the '039 Patent contemplate that the maytansinoid drugs that Doctor Lambert was discussing could be used as drug moieties for an ADC?

A. Yes, it does.

Q. How does it describe that?

A. This section shows an antibody linked via the disulfide linker SPP to the maytansinoid drug moity DM1 is advancing into phase 2 trials.

Q. And so was the technology for thiol linking known as of the time of this patent and contemplated by the patent?

A. Yes. That disulfide linker that the statement refers to is an example of thiol conjugation.

Q. And could the thiol group be used with the peptide linkers disclosed in the patent?

A. Yes, it could.

Q. All right. Let's go now back to Doctor Lambert's slide,

alcohols.

Was the chemistry for conjugating drugs with alcohol groups to an antibody known as of 2004?

A. Yes, it was.

Q. And was it contemplated by the 2004 patent application and the '039 Patent?

A. Yes, it was.

Q. Is there a particular article in the '039 Patent and the original disclosure that discusses such chemistry?

A. Yes, there is.

Q. And who were the authors of that article?

A. Doctor Toki was the lead author.

Q. And is he one of the inventors of the 2004 patent application and the '039 Patent?

A. Yes, he is.

Q. Was that the JOC article from 2002 that Doctor Toki discussed in his deposition testimony that was just played for everyone today?

A. Yes, that was the article.

Q. And what -- what conjugation strategies does that article discuss at a high level? Maybe it would help if we pull it up.

I don't actually have the exhibit number right here. Perhaps you could just discuss it at a high level, Doctor Bertozzi.

A. That 2002 article that Doctor Toki authored describes the conjugation of drugs with alcohol functional groups to linkers for use in ADCs.

Q. And did it discuss ether linkages?

A. Yes.

Q. Can you describe about an ether linkage and how it could be useful in conjugating an alcohol?

A. Yes. An ether linkage is what is formed when a drug has a so-called hydroxy group and you want to link that hydroxy group to an element from the remainder of the linker, and the ether is the bond that's formed.

Q. My team helpfully provided me with an exhibit number. Here it's Plaintiff's 536.

Doctor Bertozzi, could you just read off the journal here and explain to us what this journal is?

A. This is the Journal of Organic Chemistry, and it is one of the most important journals in the field of organic chemistry.

Q. And so when Doctor Toki was referring in his testimony to JOC, was he referring to this journal?

A. Yes, this is the journal.

MR. CHIVVIS: Let's flip to the next page; probably a page further. I'm looking for the first page of the article.

Q. (BY MR. CHIVVIS) So what does the title of this

particular publication tell us about the topic that Doctor Toki was investigating here?

A. Well, the title is, "Protease-Mediated Fragmentation of Para-Aminobenzyl Ethers, a New Strategy for the Activation of Anticancer Prodrugs."

Q. And discussing ethers here, what import does that have for conjugating drugs with alcohol groups?

A. Doctor Toki shows in this paper the chemistry for taking drugs with alcohols and connecting them to linkers with the ether bond.

Q. Doctor, is this publication specifically referenced in the 2004 patent application and the '039 Patent?

A. Yes. This reference is provided in both of those patent applications and the issued patent.

MR. CHIVVIS: If we look at the '039 Patent at, I believe, column 68. And if you'll scroll down a bit, Mr. Lee.

Q. (BY MR. CHIVVIS) Right around lines 55, do we see here confirmation, Doctor Bertozzi, that this article is specifically referenced in the '039 Patent application?

A. Yes. That is the reference to Doctor Toki's 2002 paper.

Q. And would the same reference appear in the 2004 patent application?

A. Yes, the same reference is in the 2004 patent application.

Q. Doctor Bertozzi, have you done an analysis to determine

whether a representative number of species of drugs could be attached to a linker based on what you -- the linker claimed in the '039 Patent, based on what you find in the four corners of the 2004 patent application?

A. Yes.

Q. And what did you find?

A. What I find is that the specifications of the '039 Patent and the 2004 patent application provide all of the information necessary to conjugate those listed drugs to the linkers that are shown.

Q. And would that include drugs with an amine group for attachment to the linker?

A. Yes.

Q. And would it include drugs with alcohol groups for attachment to the linker?

A. Yes.

Q. How many drugs have those functionalities such that they could be attached in the fashion described in the '039 Patent and the 2004 patent application?

A. Many drugs have those functional groups and can be readily attached to the linkers.

Q. Can you estimate? Is it more than a hundred?

A. It's hard to estimate. I mean, there are many dozens of drugs that have those functional groups.

Q. Doctor, are there common structural features of drugs

with these functionalities such that a POSA, a person of ordinary skill in the art, would be able to visualize and recognize drugs that could be attached using the linker described in the '039 Patent claims?

A. Yes.

Q. What are those?

A. Well, the person of ordinary skill would look at the structure of a drug of interest. Many drugs already have the chemical groups necessary to do the conjugation, and most drugs can be modified if they don't have the preferred functional group in order to introduce the preferred functional group.

So any one of those many drugs that are listed would be conjugatable using the knowledge that's provided by that person of skill.

Q. Doctor, would that work require undue experimentation?

A. No.

Q. Why not?

A. It would not because the chemistry to do these conjugations is well-known in the organic chemistry field. These chemistries are many decades old. They were developed before the field of ADCs even started. And that chemistry is something that we learn in our training as chemists when we're undergraduates, for the most part.

Q. So you're a professor, Doctor Bertozzi. Is this

something you train chemists in before they've even gotten their Ph.D.s?

A. Yes. The chemistries that we've discussed are the type of chemistry that we would teach in a freshman laboratory.

Q. And, Doctor, you heard Doctor Lambert's definition of who the person of ordinary skill in the art is. Do you agree with it?

A. Well, I, for the most part, agree with it, yeah.

Q. And would that person have more skill than a freshman taking college chemistry?

A. No, the person of skill, as Doctor Lambert articulated it, is a person with an advanced degree.

Q. Right. And so they would have -- would they have far more skill than the freshman in a college chemistry class?

A. Yes, they would.

Q. All right. I'd like to turn to another topic here.

MR. CHIVVIS: Let's pull up Doctor Lambert's slide No. 35.

Q. (BY MR. CHIVVIS) Now, Doctor Bertozzi, you recall when Doctor Lambert criticized your analysis of the Miyasaki lab notebook?

A. Yes.

Q. Do you agree with his criticisms?

A. No, I don't.

Q. Do you recall when he said that the reference to SG-type

in the Miyasaki lab notebook was general and not specific to any Seagen confidential information?

A. Yes, I recall that testimony.

Q. Do you agree with that?

A. No, I don't.

Q. How do we know?

A. Well, I've analyzed the evidence.

Q. And did you rely just solely on the words 'SG-type' in the laboratory notebooks, or did you peer deeper than that?

A. I analyzed deeper than that.

Q. All right. Let's take a look at your analysis.

MR. CHIVVIS: I'd like to pull up PX 724. This is one of the laboratory notebooks of Doctor Miyasaki. And if we could go to page 8 of this exhibit, and it's page 22 of the notebook, I think. There we go. That's what I was hoping to focus on. Page 6. Excuse me. Page 6 of Exhibit 724. Page 22 of his laboratory notebook.

Q. (BY MR. CHIVVIS) Now here, Doctor, do we see one of those references to SG-type conjugation?

A. Yes, we do.

Q. And was that a general reference to a publicly-available method, or was it to a proprietary and confidential method that Seagen shared with Daiichi Sankyo?

MR. RATLIFF: Objection, Your Honor. We're in the validity case here, and so it's outside -- beyond the scope,

Your Honor.

THE COURT: We're in the rebuttal case. It addresses both infringement and validity. That's overruled.

MR. CHIVVIS: And, counsel, since you paused at this time, is this something you want the courtroom sealed for?

MR. RATLIFF: If you're going further.

Your Honor, could we request to have the Court sealed if he's going into confidential information?

THE COURT: You may request the Court to seal the courtroom. And based on that request, I will order the courtroom sealed and direct that all persons present who are not subject to the existing protective order that's been entered in this case excuse themselves until the courtroom is reopened and unsealed.

(Courtroom sealed.)

(Courtroom unsealed.)

THE COURT: All right, counsel. Continue, please.

Q. (BY MR. RATLIFF) So let's turn our attention to the last page of the patent-in-suit and let's look at claim 1.

Now, Doctor Bertozzi, you'll agree with me that claim 1 does not contain any synthesis method. Correct?

A. That is correct.

Q. And you would agree with me that claim 1 does not contain

any reference to TCEP. Correct?
A. That is correct.
Q. And you would agree with me that claim 1 does not contain any reference to a reaction time. Correct?
A. That is correct.
Q. And you would agree with me that claim 1 does not contain any reference to a stock solution. Correct?
A. That is correct.
Q. And you would agree with me that claim 1 does not contain any reference to a change in a reaction time. Correct?
A. That is correct.
Q. And you would agree with me that claim 1 does not refer to this term NAC. Correct?
A. That is correct.
Q. And you would agree with me that claim 1 does not refer to any quenching reaction. Correct?
A. Claim 1 does not.
Q. And you would agree with me that claim 1 does not refer to any of these parameters that you just testified about that was supposedly duplicated. Correct?
A. That is correct.
Q. Now, you understand, Doctor Bertozzi, that a United States patent only allows someone to exclude others from doing what's in the patent, what's covered by the patent. Correct?
A. My understanding is that a U.S. patent excludes others

from doing what's in the claims.
Q. Understood. And none of these reaction times, methods, and processes that you just talked about in your direct are included in the claim. Right?
A. That is correct.
Q. Now, let's look at this claim. And you would agree, Doctor Bertozzi, that the claims of this patent require an ADC with a G/F-only tetrapeptide. Correct?
A. That is a synopsis of parts of claim 1.
Q. And you agree, Doctor Bertozzi, that the patent specification of the '039 Patent does not contain any example of an ADC with a G/F-only tetrapeptide. Correct?
A. I don't fully agree with that.
Q. So can you point me to an example of an ADC that includes a G/F-only tetrapeptide in the patent?
A. I think we should look at the patent document and go to the section that I previously showed which shows the description of the peptide backbone as a di, tri, tetra, penta, et cetera, including a tetrapeptide as well as options for choosing amino acids that includes glycine and phenylalanine, and the G/F-only tetrapeptide is part of that description.
Q. So, Doctor Bertozzi, you have a copy of the patent with you. Point us to the example in the patent of an actual ADC made with a G/F-only tetrapeptide.

A. I need the document to come up on the screen. Can someone provide that for me?

Q. The patent is being displayed.

A. Well, the claims of the patent are being displayed, but I would like to refer to the section of the patent that describes --

THE COURT: Excuse me. Does the witness have a hard copy of the patent in the binders that are on the bench?

MR. RATLIFF: The witness does, yes, Your Honor.

THE COURT: Refer her to the hard copy of the patent so she can look through it.

Q. (BY MR. RATLIFF) So, Doctor Bertozzi, if you would please take a look in your binder, it should be DX 1, which is a copy of the patent-in-suit.

And the question, Doctor Bertozzi, is --

THE COURT: I think we all heard the question. Give her a minute to find it.

MR. RATLIFF: Thank you, Your Honor.

THE WITNESS: Okay. If I could turn the monitor to in the exhibit, it looks like it's page 79.

MR. RATLIFF: So let's turn to page 79, Mr. Campos.

THE WITNESS: And at the bottom of that page, section 932, there is described amino acid spacers, a tetrapeptide is an option, and among the amino acids that one can use are included glycine and phenylalanine, which are the

R19 groups of hydrogen and benzyl.

Q. (BY MR. RATLIFF) And are you finished with your response, Doctor Bertozzi?

A. Yes.

Q. Okay. So let me ask my question a little bit differently. Can you show us any example of an actual ADC that includes a G/F-only tetrapeptide in the patent specification of the '039 Patent?

A. I think to answer the question most accurately, I have to understand what you mean by example.

Q. An actual ADC showing an antibody, a linker, and a drug. Is there any example, Doctor Bertozzi, of an antibody and a drug linker wherein the drug linker includes a G/F-only tetrapeptide in this patent?

A. There is no structure of such an ADC shown in this patent.

Q. Now, Doctor Bertozzi, you spoke earlier about the person of ordinary skill in the art. Right?

A. Correct.

Q. And is this person of ordinary skill in the art smarter than Doctor Senter?

A. There's a lot of smart people in the world.

MR. RATLIFF: Objection, non-responsive.

THE COURT: Well, you're asking her to speculate about Doctor Senter's intelligence. I don't know how that's a

proper question.
Q. (BY MR. RATLIFF) Well, Doctor Bertozzi, let me ask this. So are you testifying here today that Doctor Senter, it took him 15 years to include in his patent a claim to an ADC with a G/F-only tetrapeptide, but the person of ordinary skill in the art would see it and do it much sooner? Is that your testimony?
MR. CHIVVIS: Objection, argumentative.
THE WITNESS: That's a mischaracterization of my testimony.
THE COURT: Just a minute, Doctor Bertozzi.
THE WITNESS: Oh, I'm sorry.
THE COURT: The objection is overruled.
Now please answer the question.
THE WITNESS: I would say that is a mischaracterization of my testimony.
Q. (BY MR. RATLIFF) Okay. Well, now, you were here when Doctor Senter testified on Monday. Correct?
A. Yes, I was.
Q. And I take it that you believe Doctor Senter was being truthful when he gave sworn testimony. Correct?
A. Yes, I do.
Q. And so you believe that Doctor Senter was being truthful when he gave sworn testimony that Seagen wasn't the first to think of an ADC having a G/F-only tetrapeptide. Correct?

A. I believe that he was testifying truthfully to the best of his ability.
Q. And you believe that Doctor Senter was testifying truthfully to his ability when he said that the first time he had ever saw a tetrapeptide in an ADC G/F-only, it was in Daiichi Sankyo's Enhertu. Right?
A. I recall that's what he said.
Q. And I take it you believe that Doctor Senter was being truthful when he testified that at the time of the original 2004 application, Seagen had never seen and specified a G/F-only tetrapeptide. Right?
A. I believe he was being truthful when he said that.
Q. And I take it, Doctor Bertozzi, that you believe that Doctor Senter was being truthful when he testified that when he filed the original patent in 2004, he didn't specify Daiichi Sankyo's G/F-only tetrapeptide because Seagen wasn't aware of it at the time of the filing. Right?
A. I don't recall exactly how he phrased it.
Q. Well, Doctor Bertozzi, I take it that you believe Doctor Senter was being truthful when he testified that in Seagen's work that led to -- that led up to the 2019 filed patent, no one within Seagen made G/F-only tetrapeptides. Right?
A. I believe he was testifying truthfully, yes.
Q. And I take it, Doctor Bertozzi, that when you heard Doctor Senter testify, you think he was being truthful when he

said that the specification for his patent does not disclose anywhere the particular subgenus of 81 tetrapeptides with only G and F. Right?

A. I believe Doctor Senter testified truthfully.

Q. And, Doctor Bertozzi, I take it that you also believed that Doctor Senter testified truthfully when he said if he were in possession of an ADC with G/F-only tetrapeptides, he could have added a G/F-only tetrapeptide as an example to the original application. Right?

MR. CHIVVIS: Objection, Your Honor.

THE COURT: State your objection.

MR. CHIVVIS: Cumulative, 403. This testimony, it's in evidence, but to have him publish Doctor Senter's testimony through the witness, I think it's gotten to the point that it --

THE COURT: I'm going to direct the witness [sic] to move on. This is not an opportunity to republish Doctor Senter's testimony through somebody else. You need to ask questions within the personal knowledge of this witness.

Q. (BY MR. RATLIFF) Doctor Bertozzi --

MR. RATLIFF: Thank you, Your Honor.

Q. (BY MR. RATLIFF) Doctor Bertozzi, now you were here at the opening. Correct?

A. Yes, I was.

Q. And you saw in the opening that the Plaintiff Seagen held

up a copy of the '039 Patent with the ribbon. Correct? Did you see that?

A. I can't recall exactly that moment.

Q. Now, but you've read the '039 Patent. Correct?

A. Yes.

Q. And you realize that it's 200 pages. Correct?

A. Something like that.

Q. And are you aware of any limitation on the amount of pages that can be in a patent?

A. I am aware of situations in which a person should -- is asked to reduce the length of their patent.

Q. Now, in this 200 pages in the patent, do you find any example where the inventors actually made an ADC with a G/F-only tetrapeptide?

A. Can you rephrase the question? Or repeat the question?

Q. Sure. In the patent that's over 200 pages, you didn't see any example of an actual ADC made with a G/F-only tetrapeptide. Correct?

A. That's correct.

Q. Now, you would agree, Doctor Bertozzi, that our patent system seeks to reward the first inventor. Correct?

A. That is true.

Q. And you would agree that, while the jury has heard the testimony over these days, this is testimony that the Patent Office didn't hear. Correct?

A. The Patent Office is not here in the courtroom, to my knowledge.

Q. And based upon all that you've heard, Doctor Bertozzi, would you agree that the first company in this lawsuit to think of and be in possession of an ADC with G/F-only tetrapeptides is Daiichi Sankyo?

A. No, I disagree.

Q. So, in your opinion, Seagen was the first to think of an ADC with a G/F-only tetrapeptide, even though they had never made that tetrapeptide before the filing of the patent. Correct?

A. Seagen conceived of an ADC with a peptide protease cleavable peptide linker, among other components, and the G/F-only tetrapeptide falls within that invention.

Q. Now, Doctor Bertozzi, let's bring up one of your slides, PDX 3.29. Now, here you're showing a page from a laboratory notebook of Doctor Kline. Right?

A. Yes.

Q. And you say here at the top that Doctor Kline made tetrapeptide linker for use in ADCs. Right?

A. Yes.

Q. Now, this notebook page does not show any actual ADC. Correct?

A. This page does not show the ADC. Correct.

Q. And this notebook page does not show any ADC with a

G/F-only tetrapeptide. Correct?
A. That's correct.
Q. And this page does not even show a G/F-only tetrapeptide. Correct?
A. That is correct.
Q. And in your slides that you showed to all of us, you don't show any evidence that Doctor Kline ever made an ADC with a G/F-only tetrapeptide. Correct?
A. That's correct.
Q. Now, in your slides, you don't show to any of us that there's evidence that anyone at Seagen ever made an ADC with a G/F-only tetrapeptide before Daiichi Sankyo. Correct?
A. I have not seen evidence that they have or did.
Q. Now, and even you agree, Doctor Bertozzi, that an ADC made with this GSVQ tetrapeptide, that there's no data for such an ADC in the '039 Patent. Correct?
A. Can you clarify that question, what -- what you mean by 'data'?
Q. There's no biological testing of an ADC made with this sequence GSVQ. Correct?
A. I don't know if they evaluated their ADCs at Seagen, but I think --
Q. You didn't see any data for an ADC with that sequence in the '039 Patent. Correct?
A. Not in the '039 Patent. Correct.

Q. Now let's bring up your slide, it's PDX 3.28.

Now, is -- this is a Science Day presentation by one of the inventors. Correct?

A. Correct.

Q. Now, and you showed this page to us before. Correct?

A. Yes, I did.

Q. Now, none of the sequences listed on this page are even tetrapeptides. Right?

A. That's correct.

Q. And so that means that none of the sequences on this page are a G/F-only tetrapeptide. Correct?

A. That's correct.

Q. Now, you pointed out some sequences here, and they're dipeptides indicated by your box on the right in the red color. Correct?

A. Those are three dipeptides that I highlighted.

Q. Now, let's turn our attention to the first dipeptide that you highlighted, the GG dipeptide.

Now, that dipeptide is not even included in Seagen's patent. Correct?

A. I'd have to go back and check to make sure.

Q. Now, let's take a look at the second one. The FF dipeptide, that's not included in Seagen's patent. Correct?

A. I think I misspoke. Actually all of these dipeptides are included in Seagen's patent, at least all the ones with the

natural amino acids are included in Seagen's patents.
Q. Okay. So it's your belief that all of these dipeptides are included in Seagen's patent. Correct?
A. Yes.
Q. But none of them are the G/F-only tetrapeptides that are part of the patent claim. Correct?
A. No, these are dipeptides.
Q. Now, your slides don't show any evidence that Seagen ever made a GFLG ADC. Correct?
A. Can you repeat the question one more time?
Q. I'll try it this way.
Now, you testified about GFLG. Correct?
A. That sequence has come up in my testimony, yes.
Q. Yes. And a GFLG tetrapeptide is not a G/F-only tetrapeptide. Correct?
A. That's correct.
Q. Now, your slides don't show anywhere evidence that Seagen ever made an ADC with a GFLG tetrapeptide before the 2004 original filing. Right?
A. Can you repeat the beginning of the question again?
Q. Your slides do not show evidence anywhere that Seagen ever made a GFLG targeted ADC before the original 2004 filing. Correct?
A. I think that is correct.
Q. Now, the GFLG sequence, you would agree that it's not a

sequence that was invented by the inventors of the '039 Patent. Correct?

A. Well, it's just a peptide sequence, so it's hard to answer the question.

Q. And it was a peptide sequence that was in the prior art. Correct?

A. That peptide sequence had been reported in the prior art, yes.

Q. Right. And it had been reported in the prior art by other scientists. Correct?

A. Yes, several scientists had relied on that sequence.

Q. Now, Doctor Bertozzi, I want to turn your attention to --

MR. RATLIFF: Let's bring up DX 596. And let's enlarge it so you can see it.

Q. (BY MR. RATLIFF) Now, Doctor Bertozzi, you recognize a copy of this patent. Right?

A. Yes, I do.

Q. And this patent issued in April of 2001. Correct?

A. That is correct.

Q. And so this patent issued three years before the filing of the original application for -- that Seagen made. Correct?

A. That's correct.

Q. And when you look at the inventors listed here, none of the inventors are the inventors on the Seagen patent. Correct?

A. These are inventors from Bristol Myers Squibb, so you are correct.

Q. Now, let's turn our attention in this patent to lines 4 -- or to column 4 and then lines 34 to 44. And do you see on the screen, Doctor Bertozzi, that GFLG sequence that you mentioned before?

A. Yes, I do.

MR. RATLIFF: And we can highlight that. I believe it's right there in the middle.

Q. (BY MR. RATLIFF) So the inventors of the '039 Patent, they hadn't come up with the sequence GFLG. Correct?

A. I can't really answer the question as you phrased it accurately with a yes or no.

Q. Well, the GFLG sequence was known before the inventors of the '039 Patent filed the 2004 application. Correct?

A. The sequence was known in other contexts outside of the construct of the Seagen linker, yes.

Q. And let's step back out. This '345 Patent that we're looking at, this is a patent relating to ADCs. Correct?

A. Yes, this relates to ADCs.

Q. Now, Doctor Bertozzi, let's bring up DDX 4.40. It's one of Doctor Lambert's slides. And let's take a look at the first bullet point on this timeline.

And looking at this timeline, you agree, Doctor Bertozzi, that Seagen filed its original application in November of

2004. Correct?
A. That's correct.
Q. And you agree, and we've seen it before, that Daiichi Sankyo publicly presented in, December 2015, Enhertu. Correct?
A. Yes, that's correct.
Q. And you agree that Seagen's patent, the one that resulted in the patent in this lawsuit, was filed in July of 2019. Correct?
A. Yes, '039 was filed in 2019.
Q. Now, on this issue of who was the first to be in possession to conceive and think of an ADC with a G/F-only tetrapeptide, it was Daiichi Sankyo. Correct?
A. I disagree.
Q. Now, Doctor Bertozzi, based upon all the testimony that we've heard today, do you -- have you looked at -- let me ask you a different question.

Now, I'm going to ask you a question about the -- let me ask the question about Seagen's patent claims.

You would agree, Doctor Bertozzi, that Seagen does not have any FDA-approved drug that is covered by its patent claims.
A. Can you be more specific about the patent claims?
Q. I'm talking about the '039 Patent. So with respect to the '039 Patent, the patent that is the subject of this

lawsuit, you agree, Doctor Bertozzi, that Seagen has not ever made an FDA-approved ADC that falls within the scope of that patent. Correct?

A. That's correct.

MR. RATLIFF: Your Honor, I pass the witness.

THE COURT: All right. Further cross-examination?

MR. CHIVVIS: Redirect, Your Honor.

THE COURT: I'm sorry; redirect.

MR. CHIVVIS: Yes; brief.

THE COURT: I'm sure it was my hunger that caused me to misstate that.

Go ahead, counsel.

MR. CHIVVIS: Thank you, Your Honor.

REDIRECT EXAMINATION

BY MR. CHIVVIS:

Q. Doctor, I think a few points of clarity may be helpful here, so I'd like to ask you this.

In order to be entitled to a United States patent, do you actually have to make a physical embodiment of your patent claim, or is it enough to conceive of it and disclose it in your patent application, Doctor Bertozzi?

A. You do not have to make the specific, for example, ADC that is claimed. It is enough that you conceive of it and describe it in the detail that would be required for a person of ordinary skill to practice it.

Q. And, Doctor, to be entitled to a United States patent that claims ADCs, or pharmaceutical products--let's broaden it--do you actually have to get an FDA approval first?
A. No, no FDA approval is necessary.
Q. And, Doctor, are there patents within the same family as the '039 Patent which cover Seagen's ADC products?
A. Yes, there are.
MR. CHIVVIS: I'd like to go to one of the slides that opposing counsel just put up here. It's No. 40 from Lambert -- Doctor Lambert's testimony.
Q. (BY MR. CHIVVIS) Remember this slide, Doctor Bertozzi?
A. Yes, I do.
Q. Do you see a curious gap in the slide in the timeline?
A. If you're referring to the gap between the 2004 bullet and the 2015 bullet, yes.
Q. What happened during that gap?
A. Well, that was the gap during which Daiichi Sankyo reached out to Seagen, formed the collaboration with Seagen in 2009, and then -- sorry, 2006. They formed the collaboration in 2006. In 2009 or 2010, they also formed their own internal working group that worked in parallel with the Seagen collaboration. Then they terminated the collaboration in 2015, a few months before this bullet of presenting Enhertu to the public.
Q. And just for the record, Doctor Bertozzi, if the jury

wanted to look at that termination letter, could they look again at PX 844?

A. That sounds right.

MR. CHIVVIS: Nothing further, Your Honor.

THE COURT: You pass the witness?

MR. CHIVVIS: Yes.

THE COURT: Do you have further cross-examination of this witness, Mr. Ratliff?

MR. RATLIFF: Yes, Your Honor.

THE COURT: All right.

MR. RATLIFF: Mr. Campos --

THE COURT: Just a minute. Let's let opposing counsel get seated.

All right. Please proceed.

MR. RATLIFF: Thank you, Your Honor.

Mr. Campos, let's bring up that same slide, DDX 4.40.

RECROSS EXAMINATION

BY MR. RATLIFF:

Q. Now, Doctor Bertozzi, on this timeline, you understand that on March -- in March of 2019 is when Daiichi Sankyo and AstraZeneca announced a collaboration with respect to Enhertu. Correct?

A. That is my understanding.

Q. And it's also your understanding--correct?--that before that time, Seagen had never presented to the Patent Office a

claim for an ADC with respect to a G/F-only tetrapeptide. Correct?

A. Yes, that's my understanding.

Q. But you understand that Seagen is in this court today saying that it was in possession, it had conceived of and thought of an ADC with a G/F-only tetrapeptide going all the way back to November of 2004. Correct?

A. That's correct.

Q. But you also understand that as of December of 2015, Seagen had publicly saw Daiichi Sankyo's Enhertu. Correct?

A. That's my understanding.

Q. And you also understand that in the 2017 time period, Seagen was analyzing Daiichi Sankyo's drug linker for Enhertu. Correct?

A. I've heard testimony to that effect.

Q. And you also understand, Doctor Bertozzi, that in 2016, 2017, and 2018, there was never any claim presented to the Patent Office for an ADC with a G/F-only tetrapeptide. Correct?

A. I've heard testimony to that effect.

Q. And you also understand that you haven't seen any document before that March 2019 date that's on this timeline where Seagen was ever saying that Daiichi Sankyo's drug linker was Seagen's drug linker. Correct?

A. I lost the first part of the question. Can you repeat

it?
Q. Before March of 2019, you have never seen any document in your review of documents in this case of Seagen ever saying that Daiichi Sankyo's drug linker was Seagen's drug linker. Correct?
A. I just can't follow this question. Can you shorten it a little bit into parts?
Q. Let's try it this way. In all your review of documents in this case, before March of 2019 have you ever seen a document that doesn't describe the Daiichi Sankyo drug linker as a drug linker that's owned by Daiichi Sankyo?
A. Let me see if I understand the question. Are you asking me if I have ever seen a document that doesn't describe Enhertu as -- I'm sorry. I'm having a hard time following the question.
Q. We'll shorten it and leave it with this. Doctor Bertozzi, the first time that you've ever seen Seagen seek a claim to an ADC with a G/F-only tetrapeptide is after this March 2019 date. Correct?
A. That would be in the '039 Patent application or the patent application leading to the '039 Patent.
MR. RATLIFF: I pass the witness, Your Honor.
THE COURT: All right.
MR. CHIVVIS: Nothing further, Your Honor.
THE COURT: No redirect?

MR. CHIVVIS: Correct, Your Honor.

THE COURT: All right. You may step down, Doctor Bertozzi.

MR. CHIVVIS: Your Honor, may the witness be excused?

THE COURT: Any objection?

MR. RATLIFF: No, Your Honor.

THE COURT: Doctor Bertozzi, you are excused, which, as you've heard me tell other witnesses, you are either free to stay with us or free to leave; it's up to you.

THE WITNESS: Thank you, Your Honor.

THE COURT: You're welcome.

Ladies and gentlemen of the jury, we're going to --

Well, before we do that, Plaintiff, do you have any rebuttal -- additional rebuttal witnesses to present on the issues of liability?

MR. HILL: No, Your Honor.

THE COURT: So Plaintiff rests its rebuttal case related to liability and has nothing else related to non-damages?

MR. HILL: That's correct, Your Honor.

THE COURT: Okay. All right, ladies and gentlemen, we'll begin with the damages case, which I bifurcated, which is the legal term which means we pushed it to the end, after lunch.

You've now heard all the evidence regarding liability issues. We will take up the evidence from both parties regarding damages issues after lunch.

Lunch should be waiting for you in the jury room. In fact, I know it is. Please follow all my instructions over this break, including not to discuss the case with each other. It is 12:20 by my clock. We'll attempt to reconvene shortly between 10 after 1:00 and 1:20, 50 to 60 minutes from now.

With that, ladies and gentlemen, the jury's excused for lunch.

(Whereupon, the jury left the courtroom.)

THE COURT: Counsel, for your information, according to the Court's records, the Plaintiff has 2 hours and 21 minutes of remaining designated trial time, and the Defendant has 2 hours and 23 minutes of designated remaining trial time.

We'll proceed with the damages case after lunch, and we will reconvene about 1:15, 1:20.

Court stands in recess.

(Lunch recess.)

THE COURT: Be seated, please.

All right. As we move to the damages case, is Plaintiff prepared to go forward with their first damages witness?

MR. HILL: Yes, Your Honor, we are.

THE COURT: All right. And I understand Defendants' damages expert will be listening by telephone.

MR. DACUS: She is on the telephone, Your Honor.

THE COURT: Both as to Plaintiff's first witness and then as to the deposition witness?

MR. DACUS: Yes, sir.

THE COURT: All right. Let's bring in the jury, please.

(Whereupon, the jury entered the courtroom.)

THE COURT: Welcome back from lunch, ladies and gentlemen. Please have a seat.

I mentioned, when we broke for lunch, we'll now proceed to take up the damages portion of the case.

Plaintiffs, call your first witness related to damages.

MR. WILSON: Your Honor, Plaintiffs call Carrie Distler.

THE COURT: All right. Ms. Distler, if you'll come forward and be sworn by the Courtroom Deputy, please.

Counsel, you may go to the podium and prepare.

(Whereupon, the oath was administered by the Clerk.)

THE COURT: Please come around, ma'am, have a seat at the witness stand.

Are there binders to distribute to this witness?

MR. WILSON: They're on the stand already.

THE COURT: Already done. Thank you.

CARRIE DISTLER, SWORN,

testified on direct examination by Mr. Wilson as follows:

Q. Good afternoon, Ms. Distler.
A. Good afternoon.
Q. And good afternoon. I'm Bryan Wilson. I'm representing Seagen in this matter.
Ms. Distler, could you introduce yourself to the jury, please?
A. My name is Carrie Distler.
Q. And where are you from?
A. I grew up in a small town in mid Missouri, population of about 12,000.
Q. Did you go to college?
A. I did.
Q. Where did you go to college?
A. I went to the University of Missouri, Mizzou, about 30 miles from my hometown.
Q. Did you go to grad school?
A. I did.
Q. And where did you go to grad school?
A. Also at Mizzou.
MR. WILSON: Mr. Lee, could you pull up a copy of Exhibit PDX 4.2, I believe it is?
Q. (BY MR. WILSON) This is a summary of your qualifications?
A. Yes, it is.
Q. Okay. Where do you work, Ms. Distler?

A. My employer is FTI Consulting.
Q. And what is your job title with FTI Consulting?
A. It's senior managing director.
Q. How long have you worked at FTI?
A. Over 18 years now.
Q. And what do you do there?
A. I've spent my career analyzing the economic value that intellectual property adds to products and companies.
Q. What is intellectual property?
A. Intellectual property, or sometimes I'll refer to it as IP, they are assets that you can't necessarily put your hands on like a piece of equipment, like patents, trade secrets and trademarks, but they add significant value to companies and their products.
Q. Do you have any leadership roles at FTI?
A. I do.
Q. What are they?
A. I sit on the leadership team of FTI's national intellectual property practice. We are a group of 45 professionals that spend most of our time working on intellectual property issues.
Q. Have you received any public --
MR. DACUS: Pardon me for interrupting. May we approach briefly?
THE COURT: Approach the bench, counsel.

(The following was had outside the hearing of the jury.)

THE COURT: What is it, Mr. Dacus?

MR. DACUS: I'm getting a text from the witness who says she can barely hear, that it's very muffled.

THE COURT: We're doing the very best we can.

MR. DACUS: No, I understand. I was just going to ask the Court if you could ask the witness to speak directly into the microphone.

THE COURT: Rather than do that, I'm happy to have the Courtroom Deputy turn the volume up as high as we can.

MR. DACUS: I understand.

THE COURT: But our system will only do what it will do.

MR. DACUS: I know, and I'm not being critical I'm just try to make sure she can hear.

THE COURT: I want to help facilitate that.

MR. DACUS: And we don't have a real-time feed. I'm told I thought we were going to have a real-time feed, but apparently we don't have that, so she is dependent on hearing it.

THE COURT: All right. I'll ask the witness to speak up.

MR. DACUS: Thank you, Your Honor.

THE COURT: Ms. Distler, I'm going to ask you to

speak up as much as you can. That will be fine.

And same for you, Mr. Wilson.

MR. WILSON: I will do that.

THE COURT: All right. Let's proceed.

Q. (BY MR. WILSON) To make sure everybody heard, do you have any leadership roles at FTI?

A. Yes.

Q. And what are they?

A. I serve on our leadership team for our intellectual property practice. We're a group of 45 individuals that spend most of our time on IP valuation and damages.

Q. Have you received any public recognition for your work?

A. Yes.

Q. What sorts of public recognition have you received?

A. For the last seven years, I've been identified as a leading patent damages expert, and in 2021 I was recognized as a leading commercial litigation damages expert.

Q. Do you do any public speaking on intellectual property issues?

A. I do.

Q. What kind of public speaking?

A. I'll speak at conferences and on panels about intellectual property valuation and damages issues.

Q. Do you have any experience with economics of pharmaceuticals?

A. I do.
Q. Can you describe that briefly?
A. Yes. I've worked on many projects around the economics of pharmaceuticals for different types of drugs that are used to treat different types of diseases like cancers.
Q. Do you consider yourself to be an expert in any areas that are relevant to this case?
A. Yes.
Q. And what would that be?
A. I've been a practicing professional economist for the past 20 years, and I have specialized knowledge in the economics of pharmaceuticals and patent damages.
Q. Have courts ever found you to be qualified to testify as an expert in patent damages?
A. Yes.
Q. Have any courts ever found you to be not qualified to testify in the area of patent infringement damages?
A. No.
Q. Ms. Distler, what were you asked to do in this case?
A. I was asked to quantify the damages that arise from the infringement of the '039 Patent.
Q. Did you perform any sort of analysis of infringement issues or validity issues?
A. No. I would rely on a technical expert for those types of opinions.

Q. Have you made any assumptions about infringement or validity issues?
A. Yes. I assume that the '039 Patent is found valid and infringed in determining damages.
Q. And, Ms. Distler, are you being paid for your work?
A. My employer FTI is being paid.
Q. How much is FTI being paid for your work? How much do you -- do you bill by an hourly rate?
A. Yes.
Q. And what is your hourly rate?
A. My rate is $675 per hour.
Q. Does the amount that FTI bills to Seagen depend in any way on the outcome of the case?
A. No, it does not.
Q. Does your compensation turn on any way on the outcome of the case?
A. No.

MR. WILSON: Your Honor, at this point we tender Ms. Distler as an expert in patent infringement damages.

THE COURT: Is there any objection?

MR. DACUS: No objection, Your Honor.

THE COURT: Without objection, the Court will recognize this witness as an expert in patent infringement damages.

Proceed, Mr. Wilson.

Q. (BY MR. WILSON) Ms. Distler, have you reached an opinion regarding the appropriate damages in this case?
A. Yes.
Q. What types of damages did you determine are appropriate?
A. A reasonable royalty to Seagen would be appropriate in this matter.
Q. What is a royalty?
A. A royalty is a payment or a fee for the rights to use a patent.
Q. Have you prepared a slide with a summary of your damages opinion?
A. I have.
Q. Let's look at PDX 4.3. And, Ms. Distler, could you summarize your opinion as set forth on this slide?
A. In my opinion a reasonable royalty of 26.1 million to 41.8 million would be the amount that would compensate Seagen for the infringement of the '039 Patent.
Q. At a high level, how did you arrive at that number?
A. I took the sales of the accused product, Enhertu, 522.7 million, and multiplied that by a royalty rate.
Q. Generally, how do you go about reaching your opinion in a case?
A. I will understand the allegations at issue and how economic harm would come from those allegations. So in this instance, it would be the infringement of the '039 Patent. So

I assess the economic impact or damages from that infringement.

Q. Did you talk to anybody at Seagen in the course of forming your opinion?

A. Yes.

Q. Who did you speak with?

A. I spoke with multiple personnel from Seagen, from their finance group, their marketing and sales group, and also their commercial analytics group, so their market analysis group.

Q. Why did you speak with them?

A. I wanted to know more about their business from the people that work there every day. And you review a lot of documents, but it's often helpful to have a discussion to ask questions and -- and talk about certain documents.

Q. Did you follow any legal guidance in preparing your opinion?

A. Yes.

Q. And what guidance did you follow?

A. That in the instance of infringement, the patentholder should be compensated no less than a reasonable royalty.

Q. How do you get to a reasonable royalty rate?

A. There is something called a hypothetical negotiation.

Q. And what is that?

A. You imagine that Seagen and DSC are sitting across the table from each other and they have to negotiate the amount

that they would agree to pay to allow rights to the '039 Patent.

Q. You said you used the word 'imagine'. Does that mean this is something that really didn't happen?

A. That's right. The idea is to determine the amount that would have been paid had there been an agreement instead of infringement.

Q. And do you have a date for when the hypothetical negotiation would have taken place?

A. Yes. The date that the '039 Patent issued, which would be October 20th, 2020.

Q. Is the hypothetical -- in the hypothetical negotiation for this case, what would the license be for?

A. It would be a non-exclusive license to freely make, use, and sell Enhertu, the accused product, in the U.S.

Q. And how do you determine what the reasonable royalty rate should be?

A. There is a case called -- referred to as the *Georgia-Pacific* case. In that case, the Court outlined a set of factors that could be helpful in terms of arriving at a royalty rate in a hypothetical negotiation.

Q. And when you say a case, you're referring to a legal decision?

A. Yes.

Q. So a decision by a court for people who may not be

lawyers.
A. That's correct.
Q. And have you prepared a chart that summarizes these *Georgia-Pacific* factors?
A. I have.
Q. Let's take a look at that chart. It's PDX 4.5.
This falls into three columns. Can you explain the first -- first of all, why did you divide this up into three columns?
A. There are quite a few factors, and it's common to group them by particular categories just to make it easier to discuss them.
Q. The first column is headed licensing considerations. Could you describe the factors in that column?
A. Sure. So these will relate to licenses. At a high level, identify the terms of the license; and then, secondly, look at and analyze any agreements that Seagen or DSC has entered into in the past that would be useful for determining the royalty rate of the hypothetical negotiation.
Q. And then the second column is highlighted, economic considerations. Could you describe those considerations?
A. Yes. So these are going to be more business factors, so you look at the relationship between the parties, and then you would look at sales, profits, any indicators of commercial success of the accused products or other products that utilize

similar technologies.
Q. And then the third and final column is titled, benefits of the technology. Could you explain that, the factors in that column?
A. Yes. This is where you're gaining an understanding of the contribution of the patent-in-suit to the overall product.
Q. And once you've gathered all of this information, what do you do with it?
A. In the final factor, factor 15, you look at all the data that you collected and you assess the hypothetical negotiation outcome.
Q. In the course of doing that, do you consider every factor equally?
A. No. There are certain factors that may be more important depending on the situation.
MR. WILSON: And let's bring up PDX 4.6.
Q. (BY MR. WILSON) Could you describe how you looked at the factors using this as a guide, if that's useful?
A. Sure. So these were the most important factors in my analysis of the *Georgia-Pacific* factors that would derive the royalty rate. These include the state of the ADC market; seagen's license agreements; information about Enhertu, including sales; DSC's license agreements; and then, lastly, the relationship between DSC and Seagen.
Q. So starting with the first item, the ADC market, how many

ADCs have been approved by the FDA for treating cancer to date?

A. To date? 11.

Q. And have you prepared a chart showing these ADCs?

A. I have.

MR. WILSON: Let's pull up PDX 4.7, I believe it will be.

Q. (BY MR. WILSON) What have you listed on PDX 4.8?

A. This is a list of the 11 FDA-approved ADCs that are currently being used to treat cancers in the U.S.

Q. Some of the rows are highlighted in green. Why is that?

A. The green rows denote ADCs in the market that utilize Seagen's ADC linker technology. So five of the 11. Six if you assume Enhertu as well.

Q. Did Seagen develop all of these products on its own?

A. No.

Q. Okay. Could you describe, just going down through the rows that are green, which were developed by Seagen and which were developed in some other way?

A. Adcetris, No. 2, was developed solely by Seagen. No. 6, Padcev, and No. 11, Tivdak, were developed in partnership with another company. And then No. 5, Polivy, and No. 9, Blenrep, those were developed by Seagen's licensees.

Q. Have these products been successful?

A. Yes.

Q. And is Seagen being compensated in any way for the ADCs that are listed in green on PDX 4.8 here?
A. Yes. Seagen is either earning profits or sharing profits on those products or being paid a royalty.
Q. Is this information that's factored into your opinion?
A. Yes.
Q. And can you explain how?
A. The hypothetical negotiation would occur in October 2020, and at that time there were a number of ADCs on the market. So ADCs are an accepted therapy for -- for treating cancers. That would put upward pressure on the royalty rate.

Secondly, Seagen is an ADC industry leader. With the number of ADCs they have in the market, that would also put upward pressure at the hypothetical negotiation date.

Q. Did you also look at Seagen's license agreements?
A. I did.
Q. And did you learn anything about how Seagen generally approaches licensing its technology?
A. Yes.
Q. What did you learn?
A. Seagen typically enters into collaboration agreements with other companies. In those agreements, Seagen will license its ADC linker technology for a particular or specific target, like HER2, and that would be an exclusive right for that licensee to use the technology for that particular

target.
Q. We used the term 'exclusive'. What does exclusive mean in a licensing context that you used it?
A. Exclusive just means only that company, that licensee, would be allowed to use the technology for that target.
Q. And why does that matter?
A. It costs a lot of money to make a new drug or new therapy. So if the licensee is developing the product, if another were allowed to use the technology to also create a product that would compete, it could be harmful.
Q. Did you find any trends in Seagen's licensing policies over time?
A. Yes.
Q. And have you summarized those in another chart?
A. I have.
MR. WILSON: Let's take a look at PDX 4.9, please.
Q. (BY MR. WILSON) What have you illustrated in PDX 4.9, the chart that's headed Seagen's License Agreements?
A. So this is a timeline that I used to summarize Seagen's licensing history from approximately 2001 through 2021.
Q. If we start in the lower left, there's a green block with the title Early Technology Agreements. What does that signify?
A. From 2001 to approximately 2009, Seagen was developing its technology, its patents, and its know-how. In that

period, I've categorized it as early technology agreements, and the royalty rates that Seagen negotiated range from 2.75 percent to approximately 6 percent of sales in those agreements.

Q. Did you take a look at an agreement from that period of time that you believe was representative?

A. Yes.

Q. And what agreement was that?

A. The April 2002 GenenTech agreement.

Q. Moving to the right and up, the next block is labeled Clinical Period Agreements. Could you explain that?

A. Yes. I've labeled this clinical period agreements because in approximately 2009 Seagen's first ADC that was approved was in clinical trials, and it was generating positive results in those clinical trials and the market was noticing.

As a result, the royalty rates in that period were a bit higher than in the early technology agreements, so you see the step up to approximately five percent to nine percent.

Q. And will you be referring today to an agreement from that period?

A. Yes.

Q. And what agreement is that?

A. The Pfizer agreement in December 2010.

Q. And then the final green bar, again moving up from the

clinical period agreements into co-development and co-commercialization agreements, can you explain that last block in the upper right and top?

A. So with the success that Seagen was generating in the clinical trials and then the ultimate launch of its first ADC, Adcetris, there in August 2011, Seagen was able to start positioning itself in its agreements for product development, so entering into co-development and co-commercialization agreements.

In those, you -- the licensor and licensee would be working together and sharing the profits or splitting the profits, which would be a larger financial reward than a royalty rate.

Q. Is one of the agreements that you focused on for the purposes of your analysis from that last period?

A. Yes.

Q. Which agreement is that?

A. The August 2021 RemeGen agreement at the far end.

Q. And where does the hypothetical negotiation fit in with regard to timing?

A. It's in orange, October 2020, would be the hypothetical negotiation.

Q. Did your conclusions about Seagen's licensing history affect your opinions in any way?

A. Yes, I considered this.

Q. And what did you conclude from them?
A. At the hypothetical negotiation date, Seagen is entering into product agreements that, like I said, they're profit splitting, so they're a different financial reward than a royalty on net sales as part of the typical licenses.

Secondly, the hypothetical negotiation, DSC is sitting down and presenting to Seagen with a fully developed product. So it's a late-stage pharmaceutical. That would be different than nearly all of Seagen's prior agreements where they were entered into at the very beginning where the -- Seagen and its licensee were going to be developing a product.

So as a result, the royalty rates in October 2020 would be higher than what we would expect to see in any of the other agreements.

Q. Let's take a look at one of the agreements you mentioned. We'll start with the GenenTech agreement and that is PX 3.42.

MR. WILSON: If we could bring that up.

Q. (BY MR. WILSON) Could you just give us a general overview of the GenenTech agreement, not getting into the pricing yet?
A. Yes. GenenTech and Seagen entered into this agreement so that they could develop potential new ADCs using GenenTech's antibodies and Seagen's ADC linker technology.
Q. Why did you focus on the GenenTech agreement?
A. For a couple of reasons. First, GenenTech includes the

HER2 target, which is the same target as Enhertu, the accused product.

Secondly, the GenenTech agreement in 2002 was entered into at the early stages of Seagen's technology development. As a result, the royalty rates in this agreement would serve as a floor or a minimum of what the parties would have agreed to at the hypothetical negotiation.

Q. Did you create a chart to summarize how you analyzed the GenenTech agreement?

A. Yes.

MR. WILSON: And let's take a look at that. It's PDX 4.10.

Q. (BY MR. WILSON) So what is this that we put up on the screen?

A. So this is a chart I created to compare the GenenTech agreement in blue to the --

THE COURT: Let me interrupt just a minute.

Counsel, approach the bench, please.

(The following was had outside the hearing of the jury.)

THE COURT: Have you gotten any feedback from your lady? Is she hearing better?

MR. DACUS: I haven't gotten any negatives.

THE COURT: Is this material that needs to be under seal?

MR. WILSON: We were about to seal when we get to the numbers, but we will request to seal now.

THE COURT: All right. That seemed to me that is where we were headed.

MR. WILSON: Thank you.

(The following was had in the presence and hearing of the jury.)

THE COURT: All right. Let's proceed.

MR. WILSON: And, Your Honor, Plaintiffs request that the courtroom be sealed as we are getting into confidential information from here on out.

THE COURT: All right. Based on counsel's request, I will order the courtroom sealed and direct that anyone present who is not subject to the protective order that's been entered in this case should exit the courtroom and remain outside until the courtroom is reopened and unsealed.

This will also seal this portion of the transcript.

(Courtroom sealed.)

(Courtroom unsealed.)

THE COURT: All right. Let's please distribute the binders.

(The following was had out of the hearing of the jury.)

THE COURT: All right. What's your limine issue?

MR. DACUS: Yes, Your Honor. There is an agreed Motion in Limine No. 2, Your Honor, which relates to the size of the parties.

THE COURT: Right.

MR. DACUS: You may remember yesterday there was questioning about the fact that Daiichi is a large Japanese pharma company.

THE COURT: A big company, and Mr. Ratliff beat a path up here to complain about it.

MR. DACUS: Yes, sir. In addition, it's relevant to the bargaining positions of the parties at the hypothetical negotiation.

So I propose to ask four questions, and I wanted to talk with Your Honor what I'm proposing saying: Seagen itself is a large pharma company, that they are publicly traded, that they

are the tenth largest pharma or biotech company in the U.S., and one of the largest 500 companies in the world.

I think that's fair without getting into market cap numbers.

THE COURT: What's Plaintiff's response?

MR. WILSON: That sounds like a proxy for market cap numbers. I think the ruling yesterday was, it's okay to say a company is large. We don't object to that. But I think if you're talking about the relative size compared to other companies, is publicly traded and so on, that's getting into the area that the agreed motion prohibits.

THE COURT: Give me your four points again, Mr. Dacus?

MR. DACUS: I'd be happy to, Your Honor. That they are a large company.

THE COURT: This is --

MR. DACUS: Seagen.

THE COURT: Seagen.

MR. DACUS: I apologize. That Seagen is a large biotech pharma company, that they are publicly traded, that they are one of the 10 largest pharma biotechnology companies in the U.S., and one of the largest 500 companies in the world.

THE COURT: Okay.

MR. DACUS: I'm just trying to --

THE COURT: You have leave to make the first two points but not the last two points. That they're large and that they're publicly traded and stop there.

MR. DACUS: I will do that, Your Honor.

THE COURT: All right.

MR. WILSON: Thank you.

(The following was had in the presence and hearing of the jury.)

THE COURT: All right, counsel. You may proceed with cross-examination of the witness.

MR. DACUS: Thank you, Your Honor.

CROSS EXAMINATION

BY MR. DACUS:

Q. Good afternoon, Ms. Distler.

A. Good afternoon.

Q. I don't think you and I have met before today. Correct?

A. Correct.

Q. I'm Deron Dacus. I'm one of the lawyers who represents Daiichi and AstraZeneca.

A. Nice to meet you.

Q. Nice to meet you. Is it okay if I ask you a few questions about your opinions in this case?

A. Yes.

Q. You've been here for the trial. Correct?

A. Yes.

Q. And you heard the Judge's instructions at the beginning of the trial when he told the jury that they would need to assess during the course of the trial the credibility of the witnesses that take the stand. You heard him tell the jury that?

A. Yes.

Q. And one of the things he said specifically for experts is that the jury would need to assess the experience of the expert for the particular opinion that's being given in the Court. You heard him say that also. Correct?

A. I -- I believe so. I don't recall specifically, but it sounds right.

Q. Well, you certainly agree that, in determining and reviewing what an expert does, it's a fair thing for the jury to do to ask what experience that expert has in the particular opinions that are being given. That's fair. Right?

A. Generally, yes.

Q. Okay. And as I understand what you're doing here, you're asking this jury to consider your expert testimony on what these parties would have negotiated for a patent license for an ADC drug. Is that fair?

A. Yes.

Q. And it's true, if we talk about your experience, that in your professional experience, you have never negotiated a patent license for an ADC drug. Correct?

A. I have not.
Q. Okay. In fact, it's true in your professional life that you have not negotiated a patent license for any drug. Correct?
A. I have not sat at the table. Correct.
Q. Okay. Now, I want to be clear on what it is you're here to do and what you're not to do. Does that sound like a fair sort of set of rules to establish?
A. Sure.
Q. You are not here to provide any opinions on whether or not there is infringement. Correct?
A. That's correct.
Q. You're not here to provide any opinions on whether or not the patents are valid. Correct?
A. That's correct.
Q. And, candidly, if I heard you right, you assumed that there was infringement and that the patents are valid in the work that you've done in this case. Is that fair?
A. Yes. That's the standard for damages, correct.
Q. You and I can agree that if the jury finds that there is no infringement, then there are no damages. Correct?
A. Yes.
Q. Or if the jury finds that the patent is invalid, then there are no damages. Correct?
A. That's correct.

Q. So if the jury finds either one of those, with all due respect to you, they can sort of ignore your testimony in this case. Is that true?
A. Yes.
Q. All right. Now, what I'd like to do is talk to you about one of the topics you discussed, and that is sort of the state of the ADC market, ADCs generally. Does that sound fair?
A. Yes.
Q. To the extent that the jury's been left with the impression that Seagen has some sort of monopoly on ADCs, you would agree that's not accurate. Correct?
A. I do not state that Seagen has a monopoly.
Q. In fact, sort of the state of the ADCs today is that ADCs have actually become fairly common. Correct?
A. There are 11 approved to date.
Q. And there are more than 100 in clinical trials. True?
A. That sounds right.
Q. And there are many companies pursuing ADCs today. Correct?
A. There are a few, yes.
Q. Okay. Now, you agree in the course of your work with respect to this particular ADC that we're here about, Enhertu, that DSC--that's Daiichi--developed Enhertu, including the linker, independent of any information from Seagen. Correct?
A. Yes, I'm assuming that in my analysis.

Q. Okay. You also know from your work in this case and you've heard, I'm sure, many times in this trial that Seagen has never developed an FDA-approved product that actually uses the '039 Patent that we're here about. Correct?
A. Yes.
Q. And you agree that certainly if, in fact, Seagen had the technology that it now claims it had back in 2004, it has the resources to develop such a drug. Correct?
A. Could you read that back one time? It was a little long.
Q. I'll be happy to. You agree that if Seagen actually had this G/F-only tetrapeptide technology in the '039 Patent, it has the resources to develop a drug. Correct?
A. Yes and no.
Q. Okay. Well, you agree that Seagen is a large biotech pharmaceutical company. Correct?
A. Today they have multiple products on the market, yes.
Q. Not just multiple products. They are a large financially solvent, very solvent company. Correct?
A. Yes. Seagen is a larger company, a product company today.
Q. Seagen is publicly traded on the stock exchange. Correct?
A. Yes.
Q. Okay. So to the extent the jury's been left with some impression through the questioning in this case that Seagen is

not a large biotech pharma company, that would be incorrect. Correct?

A. Yes and no.

Q. Okay.

MR. DACUS: May I have the document camera, Ms. Brunson?

Q. (BY MR. DACUS) This is one of the slides that you showed to the jury. Correct, Ms. Distler?

A. Yes.

Q. And my assumption was that you showed this slide in some sort of effort to bolster or support the amount of money that Seagen is asking for in this case. Is that a fair assumption?

A. I would characterize it a little differently.

Q. What you told the jury, at least in part, was that this is some sort of proof that Seagen is a significant player in the ADC market. Correct?

A. Yes, an industry leader, uh-huh.

Q. Okay. But you agree that there are different types of ADCs. Fair?

A. Yes, there are.

Q. Okay. And so it is true that for each one of these -- and you highlighted the Seagen drugs in blue. Correct?

A. Or green. It looks blue, but yes.

Q. I'll tell you what I'll do so that we're clear. I'll put

a mark by the ones that I believe you highlighted as Seagen drugs. Did I mark those correctly?

A. Yes.

Q. Okay. You agree, as Doctor Bertozzi testified yesterday, that each one of those drugs is actually an auristatin. Correct?

A. No.

Q. Is it your testimony that these -- each one of these is not an auristatin?

A. I believe one of them is not an auristatin.

Q. Which one do you believe is not an auristatin?

A. I believe Blenrep.

Q. Okay. We'll leave that testimony for the jury to recall what Doctor Bertozzi said. But setting aside Blenrep, you agree the remainder of these are auristatin drugs. Correct?

A. Yes. It's my understanding the drug payload is auristatin.

Q. So if you were being more precise with the jury when you told them that, you would have said that Seagen is a leader in auristatin drugs, because that's a more accurate and truthful statement. Correct?

A. I wouldn't put it quite like that.

Q. Okay. You do agree and understand that Enhertu, the product that we're talking about here, is not an auristatin. Correct?

A. Yes.
Q. And you remember and you know from your work in this case and the testimony in this case that Seagen and Daiichi actually had a collaboration related to a potential auristatin drug. Correct?
A. Yes.
Q. And that collaboration was -- failed and terminated. Fair?
A. It was terminated, yes.
Q. Well, you heard Doctor Gormley say that the product that came from it was toxic. Correct?
A. I heard his testimony.
Q. You heard him say that it was harmful to animals and, as a result of that, they did not want to inject it into humans. Correct?
A. Yes, I heard that.
Q. And as a result of that failed collaboration, Daiichi actually went a different way than auristatins and developed Enhertu. Fair?
A. I don't know that one way or the other.
Q. Well, you know that Enhertu is not an auristatin. Correct?
A. Yes.
Q. And you know the collaboration related to auristatins. Correct?

A. And more than that is my understanding.
Q. So when the testimony in this trial by Doctor Gormley and others has been that the collaboration related to an auristatin, you're laboring under the assumption that it included more than that?
A. Yes. The Seagen ADC linker technology.
Q. Okay. I'd like to ask you some questions, if I could, about your reasonable royalty in this case.
You agree that the law allows for only a reasonable royalty. Correct?
A. Yes.
Q. And you agree that the jury should only award a reasonable royalty if it gets to that spot.
A. I would reserve the jury's decision to the jury, but yes.
Q. And you agree that it is Seagen and your burden of proof to show what the damages are. Is that fair?
A. Generally, yes.
Q. And --
MR. DACUS: May I have the document camera, Ms. Brunson?
Q. (BY MR. DACUS) You -- this is the slide that you just showed the jury. Correct?
A. Yes.
Q. In this case, you agree that a reasonable royalty would be five percent, which equates to $26 million. Correct?

A. That would be a minimum, yes.

MR. DACUS: I object as non-responsive, Your Honor.

THE COURT: Overruled.

Q. (BY MR. DACUS) You agree that the $26 million number is a reasonable royalty. Correct?

A. Yes.

Q. And you understand that Daiichi's position and their expert, Doctor Meyer, who's going to testify in just a moment, believes that the royalty rate should be one percent or in some circumstances at most two percent. You understand that?

A. Yes, that's my understanding.

Q. And ultimately the jury has to make a determination as to which one of those rates is reasonable. Is that fair?

A. They do.

Q. Now, at a high level, what you want the jury to believe here is that the '039 Patent is worth tens of millions of dollars. Fair?

A. Yes, it is.

Q. And that's what you've told them in words in your testimony today. True?

A. Yes.

Q. Do you agree that it would be fair for me as a lawyer for Daiichi to present facts to you and to the jury that show actions rather than words? Is that fair?

A. I guess I'm not sure.

Q. Okay. Let me ask -- let me -- do you live -- you live in Chicago now?
A. I actually live in Florida.
Q. Florida. Okay. In Florida. Have you -- are you familiar with the phrase the proof is in the pudding?
A. Yes, I've heard that.
Q. Okay. So that -- here when we say that, I think we mean that rather than just listen to folks' words, sometimes you should look at their actions and other actions to determine sort of where the truth lies. Does that sound like a fair thing to do?
A. Sure.
Q. Okay. You agree that Seagen, of course, is in the business of making and a selling targeted cancer therapies. Right?
A. Can you repeat that?
Q. Sure. Seagen is in the business of making and selling targeted cancer therapies.
A. Generally, yes.
Q. Okay. Well, that really -- that's their business. Correct?
A. Yes and no.
Q. Well, you actually wrote a report in this case. Correct?
A. Yes.
Q. So in this courtroom what you're required to do as an

expert is you actually have to write a written report and provide that to us in this case. Correct?

A. Yes.

Q. Okay. And you did that in this case?

A. I did.

Q. And you read it and you sign it. True?

A. Yes.

Q. And you do that to make sure that it's accurate and truthful. Correct?

A. Yes.

Q. And so in front of you is a notebook with your report in it. Can I ask you to turn to that?

A. Yes.

Q. There is a tab that says report updated, and it's dated December 13th of 2021. Do you see that?

A. Yes.

Q. And I'll ask you to turn to page 12 of that report.

A. Yes.

Q. And if you'd look at paragraph 23 of your report and read that to yourself, if you would, please.

A. Yes.

Q. Okay. Does that refresh your memory that in your report that you read and signed, that you -- that Seagen is a biotechnology company that develops and sells targeted cancer therapies?

A. Yes.
Q. So as a company in that business, even though they're in that business, they do not use this '039 Patent that's at issue in this case. Correct?
A. Yes.
Q. So what we have here is a patent that you and Seagen want the jury to believe is worth tens of millions of dollars and extends people's lives. Fair?
A. Can you ask that one more time or repeat the question?
Q. Sure. What you want the jury to believe is that the '039 Patent is worth tens of millions of dollars and is an invention that saves or at least extends people's lives with cancer. Correct?
A. Yes. My damages figure is in the tens of millions.
Q. And so if we're focusing back on the proof is in the pudding and the actions, even though that's true, even though we have a company that's business is targeted cancer therapies, they do not use the '039 Patent in this case. Correct?
A. They do not.
Q. And it's true that no company, no company in these -- in this ADC market, cancer-treating market uses this '039 Patent, do they?
A. Can you ask that one more time?
Q. Be happy to. You have no evidence that any company in

this ADC industry uses the '039 Patent. True?
A. Well, I have assumed that DSC does.
Q. Beyond your assumption that Daiichi does, no other company in this large industry uses the '039 Patent, do they?
MR. WILSON: I have to object that the question is vague in terms of use.
THE COURT: It's been asked and answered. We need to move on.
MR. DACUS: Thank you, Your Honor.
Q. (BY MR. DACUS) You know of no other product in this industry that uses this '039 Patent. Correct?
A. That's approved and sold, not that I'm aware of.
Q. Okay. Now, in addition to that, if we're just looking at a high level, you know from your work in this case that there have been lots of articles and lots of literature written about ADCs over the past couple of decades. True?
A. Yes.
Q. You've reviewed lots of articles and publications related to ADCs in the course of your work in this case. Fair?
A. I have reviewed many.
Q. I mean, this is an important issue--saving or extending the lives of individuals with terminal cancer. Correct?
A. Yes.
Q. And it's true that in all of your work, you've seen no articles, no publications that comment on the '039 Patent

specifically. Correct?
A. I can't answer that question.
Q. Do you remember that you had your deposition taken in this case, Ms. Distler?
A. Yes.
Q. And so that we're clear, the deposition was an opportunity for us to have you sit and answer questions that we asked you, and you answered those questions under oath. Correct?
A. Yes.
Q. Okay. So you have a copy of your deposition in that notebook there in front of you, if you want to turn to it. Let me know when you have it and I'll refer you to the page.
A. I have it.
Q. Okay. You can turn to page 183?
A. Yes.
Q. Lines 20 through 24, and let me know when you've had an opportunity to read that.
A. I've read it, yes.
Q. Have you had an opportunity to refresh your memory on your testimony?
A. Yes.
Q. And so you agree that you're not aware of any materials or publications that you've seen that comment on the '039 Patent specifically. Correct?

A. The question you're asking me in this on page 183 is about the importance of the '039 Patent, but I thought you were just asking me generally if there were articles that mention the '039 patent.

Q. Correct. You've not shown, nor could you show this jury, any article or publication that cites to or was written about specifically the '039 Patent. Correct?

A. I have seen commentary about the '039 Patent.

Q. You've not shown this jury any publications, articles, awards, anything like that for the '039. Correct?

A. I have not shown that to the jury.

Q. Okay. Let me ask you about the specific royalty rate numbers that you used as comparables or benchmarks in this case.

As I understand what you did is you took royalty rates from other agreements, and you are asking the jury to use those as benchmarks for their determination of a royalty rate correct.

MR. WILSON: Your Honor, we request that the courtroom be sealed at this point if he's moving into specific --

THE COURT: All right. Based on counsel's request, I'll order the courtroom sealed in order to protect the confidential information.

I'll direct that anyone present who is not subject to the

protective order that's been entered in this case excuse themselves and remain outside the courtroom until it is reopened and unsealed.

(Courtroom sealed.)

(Courtroom unsealed.)

THE COURT: Plaintiffs, call your next rebuttal witness.

MR. WILSON: Next rebuttal witness is Todd Simpson by deposition.

THE COURT: And this is your witness?

MR. WILSON: That's right.

THE COURT: All right. Let's proceed with the witness by deposition.

Actually, it's not a rebuttal witness. It's a damages witness in the Plaintiff's case in chief regarding damages.

MR. WILSON: I misspoke. Thank you for correcting.

THE COURT: It's quite understandable, given the way things have gone.

Are we prepared to go forward with this witness by deposition?

MR. HILL: Yes, Your Honor. One point of clarification. Mr. Simpson's deposition clip is actually a Defendants' witness call, as I understand it. So I wanted to --

THE COURT: I thought that, too. That's why I asked Mr. Wilson about it. Let's clear the record and let's try to start over.

Does Plaintiff have additional damages witnesses to call?

MR. WILSON: No. I'm sorry --

THE COURT: So Plaintiff rests its damages case in chief.

MR. WILSON: That is correct, Your Honor, and I apologize for the confusion.

THE COURT: That's all right.

Are Defendants prepared to go forward with their case in chief on the issue of damages?

MS. AINSWORTH: We are, Your Honor.

THE COURT: And is Mr. Simpson's deposition your first damages witness?

MS. AINSWORTH: It is, Your Honor.

THE COURT: And it's about what length?

MS. AINSWORTH: It is 14 minutes, Your Honor.

THE COURT: All right. We'll hear this witness by deposition, and then we'll take a recess.

Let's proceed with the Defendants' deposition witness.

MS. AINSWORTH: Yes, Your Honor. By agreement with Plaintiff's counsel, they have requested that this deposition be sealed.

THE COURT: All right. You want to introduce the witness, and then I'll seal the courtroom?

MS. AINSWORTH: Yes, Your Honor. As its first damages witness, Defendants call Mr. Todd Simpson, who is the chief financial officer of Seagen and testified as its corporate representative.

The deposition is 14 minutes. And, Your Honor, it's 15 minutes. Fourteen minutes and 33 seconds are Defendants' designations. One minute and 12 seconds are Plaintiff's designations.

THE COURT: Are there any exhibits you need to note?

MS. AINSWORTH: Defendants' Exhibit 1, Defendants' Exhibit 675, and Defendants' Exhibit 676.

THE COURT: All right. At counsel's request, I'll order the courtroom sealed and direct the Court Security Officer to accompany any persons present not subject to the protective order outside the courtroom until it's reopened and

unsealed.

(Courtroom sealed.)

(Courtroom unsealed.)

THE COURT: Ladies and gentlemen, we're going to take a well-deserved recess at this time. If you will, leave your notebooks closed and in your chairs. Please follow all my instructions, including not to discuss the case with each other, and we'll be back shortly to continue. With that, the jury's excused for recess at this time.

(Whereupon, the jury left the courtroom.)

THE COURT: All right, counsel. During this recess

while the jury is out of the room, let's take all steps necessary to have Doctor Meyer able to be presented by remote presentation as soon as they return.

With that, the Court stands in recess.

(Brief recess.)

THE COURT: Be seated, please.

Let's bring in the jury, please.

(Whereupon, the jury entered the courtroom.)

THE COURT: Please be seated.

Are Defendants prepared to call their next damages witness?

MR. DACUS: We are, Your Honor. At this time we would call Dr. Christine Meyer.

THE COURT: All right. I'm going to ask our Courtroom Deputy to administer the oath to Doctor Meyer. And if you'll do that where she can see you, Ms. Brunson.

(Whereupon, the oath was administered by the Clerk.)

THE COURT: All right. Mr. Dacus, you may proceed with direct examination of the witness.

MR. DACUS: Thank you, Your Honor. And does the Court need to address at all the fact that Ms. -- Doctor Meyer is appearing by video deposition?

THE COURT: Well, I mentioned that earlier to the jury, but let me just reaffirm to the jury that Doctor Meyer had intended to testify live in this case. Due to

circumstances beyond her control and the control of the parties and the Court, she's not currently able to testify live, so she's testifying remotely in the manner that you see now.

You should not pay any undue attention to that. Simply just focus on her testimony, which obviously is now going to be given under oath, and focus on the cross-examination questions that are asked by opposing counsel.

All right. Let's go forward with the direct examination, please.

MR. DACUS: Thank you, Your Honor.

CHRISTINE MEYER, PhD., SWORN,

testified on direct examination by Mr. Dacus as follows:

Q. Doctor Meyer, would you tell the jury your full name, please?

A. Christine Siegwarth Meyer.

Q. And, Doctor Meyer, would you tell the jury just a little bit about yourself?

A. Sure. I'm from a small town in New York state, moved around a lot in the United States, but now live again pretty close to where I grew up. I've got two daughters. One is in college, and one just graduated from college.

Q. And did you yourself go to college?

A. I did.

Q. Where did you go to college?

A. I went to the United States military academy at West Point.
Q. And did you get a degree from West Point?
A. I did. I got my Bachelor's degree from West Point.
Q. And after graduating from West Point, did you serve in the military?
A. I did.
Q. And how so?
A. I was commissioned as an officer in the Military Police Corps. I served in the 101st Military Police Company and the 104th Command that was attached to the 101st Airborne, both at Fort Campbell, Kentucky, and then we were deployed in the first Gulf War to Saudi Arabia and Iraq.
Q. What did you do after your military service?
A. After my military service, I went back to school and received my Ph.D. in economics from Massachusetts Institute of Technology, sometimes known as MIT.
Q. And for the testimony that you're going to give here today, Doctor Meyer, have you prepared some slides to assist with that testimony?
A. I have.
Q. After you got your Ph.D. at Massachusetts Institute of Technology, what did you do?
A. After that, I taught for five years at the university level. I taught economics and statistics. And then in the

year 2000, I started at NERA Economic Consulting where I still am today.

Q. And what is it and what kind of work do you do at NERA?

A. My title is managing director at NERA, and I'm chair of the global intellectual property practice at NERA as well. As part of that -- there's a couple of different things that I do at NERA. First of all, I'm involved in management of the firm. I sit on the board, and I have various management responsibilities.

Also, part of my work involves consulting for firms that are -- need valuation services of one sort or another. Typically, because of my role as -- in intellectual property, my valuation involves assessing the values of patents and other kinds of intellectual property, typically for use in licensing negotiation. So I do some valuations and talk strategy with companies that are going into license negotiations.

And then, third, from time to time I'm asked to, as I was here, to provide an opinion related to damages.

Q. And does your work at NERA involve the pharmaceutical industry?

A. Not all of my work relates to pharmaceutical -- the pharmaceutical industry, but quite a bit of it does, yes.

Q. And you have been retained by the Defendants in this case. Correct?

A. I have been retained on behalf of Defendants, yes.
Q. And is NERA being compensated for the time that you spend in this case?
A. Yes. I just get a salary, but NERA charges for my work at an hourly rate.
MR. DACUS: Your Honor, at this time we offer Doctor Meyer as an expert in economics and patent damages.
THE COURT: Is there objection?
MR. WILSON: No objection, Your Honor.
THE COURT: Then without objection, the Court will recognize Doctor Meyer as an expert in those designated fields.
I'm also going to ask the witness to speak a little bit slower if possible.
All right. Let's continue, Mr. Dacus.
MR. DACUS: Thank you, Your Honor.
Q. (BY MR. DACUS) Doctor Meyer, what had --
MR. WILSON: I thought we had reached a point -- the Plaintiffs request the courtroom be sealed if we're moving on to the next slide.
THE COURT: All right. Then based on counsel's request, I'll order the courtroom sealed and direct all persons present who are not subject to the protective order in the case to excuse themselves and remain outside the courtroom until it's reopened and unsealed.

(Courtroom sealed.)

(Courtroom unsealed.)

THE COURT: Ladies and gentlemen of the jury, that means you have now heard all the evidence in this case, and there are several things I must take up with counsel that don't involve the jury and we're probably going to be here late tonight getting that done. But you're not required to be here for that, and I'm about to excuse you for the day in just a couple of minutes.

I will need you back in the morning. I cannot tell you that I will be ready to go by 8:30 in the morning, and I understand that several of you don't live particularly close to this courthouse. I know it's a long way to Naples and Linden and Leesburg and places like that. So I'm going to ask that you be back in the morning and assembled in the jury room ready to go at 9:00.

And I want you to understand that that's my best estimate. I may be ready and waiting on you when you get here at 9:00. You may have to wait on me a little while, but it is, as they say, more art than it is science. But we will address -- the Court will address the things with counsel it needs to without your presence for the remainder of the

evening, and I'm going to do everything I can to be ready to go to give you -- to begin to give you my final instructions, as I told you sometimes called the Court's charge to the jury, I hope to be able to give you that at or close to 9:00 in the morning.

After I give you my final instructions, then counsel for the Plaintiff and the Defendants will present their closing arguments to you. After you've heard closing arguments from both the Plaintiff and the Defendants, then I will instruct you to retire to the jury room and to deliberate on your verdict. And I will send with you a printed verdict form that will have several questions in it, and you are to arrive at unanimous answers to those questions.

I am also, ladies and gentlemen, going to send back with you six printed copies of the instructions I'm going to give you orally, so you will each have your own printed copy of the Court's charge to the jury. I do that because I want you to listen to me as I give them to you orally tomorrow morning. I don't want you to be distracted trying to take notes or being afraid you're going to miss something. So I want you to know you'll have your own printed copy to review during your deliberations, and I'll ask that you pay particular attention as I give those instructions to you orally in the morning.

As I say, after that you'll hear closing arguments, and after that, you'll retire and deliberate on your verdict.

So that's what we have left before us. As you leave the courtroom this evening, please take your notebooks with you, leave them closed on the table in the jury room, travel safely to your homes, follow all my instructions, including not to discuss the case with anyone or with yourselves.

We are getting close to the end of the process. It would be an absolute travesty to jeopardize things by violating my instructions now. So let me just remind you one more time, don't discuss or communicate about this case with anyone, including yourselves.

With that, I hope you travel safely and have a good night, and we will see you back here in the morning at 9:00.

The jury's excused for the evening.

(Whereupon, the jury left the courtroom.)

THE COURT: Be seated, please.

Counsel, I intend to take about a 10- or 12-minute recess, and afterward I will be back on the bench at which time I intend to take up motions from either party offered pursuant to Rule 50(a) of the Federal Rules of Civil Procedure.

Local counsel who have practiced before me in the past will let you know, I'm sure, that it's my intention to identify the subject matter of any motion either party wishes to make before I hear arguments because it is quite often the most efficient way to hear concurrent and opposite arguments

on the same topic from counsel during the 50(a) process.

Also, I would remind those of you that are going to be involved in presenting motions under Rule 50(a) that I have been here the whole trial. I have heard all the evidence. Please do not get up to the podium and say, Your Honor, this is a patent case. Please don't do that. Please focus and get to the heart of your arguments as rapidly as you can, not overlooking something important, but avoiding anything extraneous.

After we've completed the offering, arguing, and the Court ruling on your motions under Rule 50(a), then I intend to meet with counsel in chambers for an informal charge conference to review those areas in the latest iteration of the proposed charge and verdict form where you're not in agreement.

And I am pleased to say that there don't appear to be a tremendous number of areas of disagreement. I am hopeful that that process will move along at a decent pace. But that informal charge conference is not only off the record in chambers, but I expect it to be casual, informal, and free-flowing. I want the full benefit of your input on any areas where you're not in agreement and any areas that I particularly want to ask about.

After I've had the benefit of your input by way of that informal charge conference, then at that point I expect to

send you home for the evening and I will be up here a while longer working on changes and edits to the charge and the verdict form that I think are appropriate based on your submissions and your input.

I would tell you that it is my hope and I believe a realistic plan that sometime tomorrow morning, probably 7:00 or 7:15, my staff and I will email each side what the Court believes the proper form of the final jury instructions and verdict form should be.

And I'm going to ask counsel to be back in the morning at 8:00. At 8:00 I intend to conduct a formal charge conference on the record where either side may offer such objections to that latest iteration of the charge and verdict form that I will email you in the morning that you believe protects the interest of your clients.

Then after I have conducted the formal charge conference, I'll make any adjustments that may be necessary and I will then produce the six copies of the printed charge and the verdict form to send back to the jury when they deliberate. And it would be my hope that we can begin with my final instructions to the jury followed by your closing arguments at or near 9:00 tomorrow morning.

It is also my practice, and again local counsel, I'm sure, are knowledgeable of this, but if you are going to participate in closing arguments, you are not required to be

present for any of these matters that we will take up this evening or tomorrow morning before I'm ready to give my final instructions to the jury. That time can be used by those of you that will present closing arguments to work on your closings and to use that time.

As a matter of fact, all I need to have are adequate representation by counsel to cover the issues that I've outlined. If you want multiple people here, that's fine. If you want one person here, that's fine. I leave that up to you. But what I've laid out is what I intend to take up after a short recess.

Do -- and I will ask this question. I'm not trying to put either side on the spot. Do you know at this point who will be presenting closing arguments for both Plaintiff and the Defendants?

MR. HILL: I think we do, Your Honor, on our side or have some general list of candidates. It will be myself and/or some combination of myself and Mr. Ward.

THE COURT: All right. Has Defendant made a decision or have a good indication of what their closing is going to be staffed?

MR. DACUS: As of now, Mr. Mann will deliver.

THE COURT: All right. And this is not written in stone. I'm just trying to get an idea.

All right. Are there any questions about what I've laid

out?

MR. DACUS: I have no questions, Your Honor, but when the Court recesses, may I address one thing in chambers with Mr. Hill and the Court? It will be very brief.

THE COURT: Yes, Mr. Dacus, that's fine. Last time you did that, we nearly lost the case, but I hope we don't have another problem. But I'll be happy to see counsel that need to see me in chambers during the recess.

And with that, the Court stands in recess.

(Brief recess.)

THE COURT: Be seated, please.

At this time the Court will take up motions from either party under Rule 50(a) of the Federal Rules of Civil Procedure.

I would like a single spokesperson for Plaintiff and a single spokesperson for Defendant to go to the microphone at the podium and identify for me the subject matter of any motions either party wishes to offer. Once I've identified the subject matter, then we'll proceed to hear appropriate argument, whether they're argued separately or concurrently, depending on the subject matter that's involved.

So with that, let me ask Plaintiff what motions, if any, under Rule 50(a) do you intend to put forward?

MR. COHEN: May I approach?

THE COURT: Please go to the podium.

MR. COHEN: Jayson Cohen for the Plaintiff Seagen, Inc.

Seagen will move for judgment as a matter of law on direct and induced infringement by DSC, and on no invalidity under Defendant's § 112 defenses, and their anticipation defense.

THE COURT: Anything else?

MR. COHEN: No, Your Honor.

THE COURT: Thank you, Mr. Cohen.

Let me ask a spokesperson for Defendants and Intervenors to identify for me any subject matter regarding which you seek to pursue a motion pursuant to Rule 50(a).

MR. FLETCHER: Good evening, Your Honor. Tom Fletcher with Williams and Connolly on behalf of the Defendants.

We have filed a written 50(a) motion. It is on the docket at Docket No. 365. If Your Honor could please acknowledge that that motion is timely filed, we'd be appreciative.

THE COURT: Well, assuming your representations are accurate, I have not taken motions up under Rule 50(a), so it would be timely.

MR. FLETCHER: Thank you, Your Honor.

At a high level, the topics addressed by our motion for judgment as a matter of law pursuant to Rule 50(a) are, first,

non-infringement under claim 1. There's no substantial evidence to find that the drug moiety Enhertu is intercellularly cleaved to release free drug.

Claim 2, no infringement. There is no substantial evidence to support a finding that Enhertu has a self-immolative spacer.

Finally, a third point, there is no substantial evidence to suggest that Daiichi Sankyo, Co., Limited, the Japanese entity, is, in fact, a direct infringer or that it has induced any infringement by Daiichi Sankyo, Inc., the U.S. entity.

Second, move for judgment as a matter of law of invalidity.

First, no reasonable jury could find that the asserted claims are entitled to the 2004 priority date based on the lack of support for the claimed genus of ADCs with a G/F-only tetrapeptide.

Because there is no 2004 priority and the asserted claims are limited to the 2019 priority date, we move for judgment as a matter of law because no reasonable jury could conclude, if they find infringement, that the Ogitani reference does not anticipate each asserted claim of the patents.

We also move for judgment as a matter of law of invalidity because the '039 Patent is invalid for its failure to describe the claimed genus of ADCs with respect to the fact that the ADCs can have any drug. Under the two-part *Ariad*

versus Lilly analysis, there are zero examples in the patent of the ADCs of the claimed genus, and there are no common features or insufficient common features to allow the person of ordinary skill in the art to visualize the ADCs of the claimed genus.

We also move for judgment as a matter of law of invalidity because no reasonable jury could conclude that the '039 Patent is not invalid for lack of enablement. There's two points under this heading.

There is no enablement in the patent to make the full scope of ADCs with any drug moiety.

The second point is that the patent would require undue experimentation to practice to identify those ADCs that meet the functional element of intracellular cleavage and separately those ADCs from those that do not meet the functional limitation of intercellular cleavage given the difficulties involved in performing assays to determine intracellular cleavage in a patient.

Two more points, Your Honor. We also move for judgment as a matter of law that no reasonable jury could find that any infringement has been willful, especially given the fact that, as Seagen has admitted multiple times in the course of this trial, they have no desire to see Enhertu removed from the market, and, in fact, are grateful that Enhertu will be available to patients. There's no change in Daiichi Sankyo's

conducts that Seagen seeks, so there can be no willful infringement.

Finally, no reasonable jury could award a reasonable royalty greater than two percent, in view of Doctor Meyer and Ms. Distler's testimony, particularly in view of Ms. Distler's failure to account for the inclusion of other patents in the licenses that she analyzed.

THE COURT: Let me ask you this Mr. Fletcher. In light of what you've just given me, do you intend to offer additional arguments? You certainly went beyond just identifying the subject matter.

MR. FLETCHER: I apologize, Your Honor. I'm happy to offer as much additional argument as Your Honor needs to make a reasoned judgment.

THE COURT: All right. Well, let's proceed.

It's clear that we have corresponding but opposite motions under Rule 50(a) between the parties with regard to the issue of infringement, both direct and induced, so let's start with that.

I'll first hear argument from Plaintiff in regard to those topics, and then I'll hear argument from Defendant, to the extent they want to offer additional argument after they've heard Plaintiff.

Mr. Cohen, please proceed.

MR. COHEN: Thank you, Your Honor.

Plaintiff has proven that Defendant DSC has directly infringed by importing Enhertu into the United States and selling Enhertu within the United States and no reasonable jury could find otherwise.

Plaintiff has proven by unrebutted DSC documents and the testimony of Mila Tartakovsky and Kevin Smith, as well as testimony of Seagen's damages expert Carrie Distler, that DSC sells vials of Enhertu to its U.S. subsidiary Daiichi Sankyo, Inc., also known as DSI, for follow-on sale to distributors in the United States. The entrustment, supply, and distribution agreements between DSC and DSI further provide incontrovertible evidence that DSC sells Enhertu within the United States within the meaning of 35 U.S.C. § 271(a).

Plaintiff has also proven by the unrebutted testimony of Kevin Smith that DSC imports Enhertu into the United States within the meaning of 35 U.S.C., § 271(a) by retaining title to the Enhertu vials it sells to DSI until those vials arrive from outside the United States to Allentown, Pennsylvania.

Plaintiff has also proven that DSI acts as DSC's agent for the sale and distribution of Enhertu to third-party customers in the United States based on the same evidence I just recited.

Plaintiff has proven -- with respect to technical infringement, Plaintiff has proven that the Enhertu vials that DSC imports into and sells within the United States satisfy

each limitation of asserted claims 1 to 5 and 9 and 10. Seagen expert Dr. Carolyn Bertozzi applied the Court's claim construction for her infringement analysis, citing Daiichi Sankyo's FDA documents like the BLA and the Enhertu product label, Daiichi Sankyo development documents including internal documents, Daiichi Sankyo publications, and Daiichi Sankyo internal and external presentations.

Dr. Carolyn Bertozzi also relied on Daiichi Sankyo witness Amita Chaudhari that Daiichi Sankyo has a robust -- sorry. Strike that. Pardon me. Let me start over on that sentence.

Dr. Carolyn Bertozzi also relied on Daiichi Sankyo witness Amita Chaudhari that Daiichi Sankyo had a robust process for ensuring that all of the information in its FDA submissions is accurate. Those FDA submissions state that Enhertu has a linker that is designed to and is cleaved after internalization into target tumor cells and has a self-immolative aminomethylene spacer.

Defendant's expert Dr. John Lambert testified that Enhertu satisfies all of the claim limitations of the asserted claims except for the two claim limitations in dispute. Doctor Lambert admitted and there's no dispute that DSC's FDA documents, including the BLA and the product label, identify Enhertu as having a free drug moiety DXd that is intercellularly cleaved from Enhertu and as having a

self-immolative aminomethylene spacer. He also admitted that DSC's FDA documents or Daiichi Sankyo's FDA documents identify MAA-1181a, another name for DXd, as the free drug released from Enhertu.

Based on this record, no reasonable jury could find that Enhertu does not meet every limitation of claims 1 to 5 and 9 and 10, and that DSC does not import Enhertu into the United States and sell Enhertu within the United States by a preponderance of the evidence.

Your Honor, that concludes our statement for direct infringement. Would you like me to proceed to induced infringement at this time?

THE COURT: I would.

MR. COHEN: Plaintiff has proven that Defendant DSC has actively induced infringement by DSI under 35 U.S.C. § 271(b). DSC had knowledge of the '039 Patent based on Seagen's filing of this action. DSC had the specific intent to induce DSI's direct infringement of the '039 Patent by DSC selling and delivering vials of Enhertu to DSI for follow-on packaging and sale of Enhertu to distributors in the United States. DSI sells Enhertu to its customers, including its distributors in the United States, making DSI a direct infringer.

The same evidence to support direct infringement that I recited previously also supports induced infringement, and no

reasonable jury could find that DSC has not actively induced DSI's direct infringement.

Thank you, Your Honor.

THE COURT: Thank you, counsel.

Let me hear any argument Defendants care to offer with regard to these issues.

MR. FLETCHER: Your Honor, I'll attempt to be brief.

On the issue of the factual basis for infringement, I believe the record shows there's no dispute that DXd is the payload that is released upon cleavage of Enhertu. However, the analysis I believe in the record shows that the drug moiety is DX, and a DX remains connected to a portion of its spacer. And based on those undisputed facts, the infringement cannot be found of either claim 1 or claim 2.

Turning to the more technical issues, the evidence has shown that the entire damages case presented by the Plaintiffs was based on the sales of Enhertu. The only sales of Enhertu that were attempted to be shown were those made by DSI, the U.S. subsidiary. There's no evidence to support direct infringement because we saw no substantive analysis of any kind that DSI makes those sales at the direction and control of DSC; rather, they are just a contractual party.

With respect to the issue of induced infringement, we heard that DSC became aware of the patent the very moment it was sued, not any before that. Induced infringement has a

much higher burden of proof, and not just that you are aware of the patent and not just that you intend for acts to be carried out, but that you intend for infringement of the patent to occur. There has been no evidence sufficient to support a finding that Daiichi Sankyo Corp.'s mental state supports a finding that it intends infringement.

That's all.

THE COURT: Thank you, counsel.

Let's move next to the invalidity arguments.

Plaintiffs move for judgment as a matter of law under Rule 50(a) with regard to no invalidity under § 102 or § 112. Defendants have moved for a finding of invalidity under § 102 as well as § 112, both enablement and written description.

Let me hear correspondingly opposed arguments on those topics, and we'll begin again with the Plaintiff.

And Plaintiff, if you would, address the priority date issue as a part of your argument.

MR. COHEN: Thank you, Your Honor.

So I'll discuss the priority issue as I -- in the context of the § 112 defenses.

So we move for judgment as a matter of law that there is insufficient evidence to prove by clear and convincing standard that the '039 Patent is invalid for inadequate written description under 35 U.S.C. § 112, and no reasonable jury could find otherwise. The following evidence shows that

Defendants have failed to carry their burden to prove inadequate written description under § 112 by clear and convincing evidence.

Doctor Lambert admitted that he did not apply the correct standard to assess the validity of the '039 Patent; instead using common sense. Doctor Lambert did not review the evidence with the understanding that the patents have a presumption of validity and that invalidity must be shown by clear and convincing evidence.

Furthermore, Doctor Lambert failed to show that the patent specification did not adequately disclose a tetrapeptide of Gs and Fs. Doctor Lambert admitted that the specification of the '039 Patent discloses the amino acid unit could be one, a tetrapeptide; and two, made of Gs and Fs.

All of the inventors of the '039 Patent also testified, as we heard today, and Doctor Senter, that the specification discloses the use of tetrapeptides as well as glycine and phenylalanine, amino acids, for the peptide unit. Doctor Doronina, Doctor Toki, and Doctor Kline further explained that the specification would direct a POSA towards tetrapeptides made of Gs and Fs.

Doctor Lambert also mischaracterized the list of drugs included in the patent that could be used as the drug moiety in the ADC, and does not otherwise dispute that the patent discloses the use of many drugs in ADC. Doctor Toki confirmed

that the patent discloses a long list of chemotherapeutic agents that could be attached to an ADC.

The testimony of Seagen expert Dr. Carolyn Bertozzi, relying on the specification of the '039 Patent and documents regarding the state of the art, also establish that a person of ordinary skill would understand that the inventors were in possession of the inventions of claims 1 to 5 and 9 and 10 as of the filing date of November 5th, 2004.

Doctor Bertozzi demonstrated that persons of ordinary skill in the art would understand that the inventors were in possession of ADC's meeting all of the limitations of the asserted claims, which includes a tetrapeptide linker consisting of only G and F amino acid residues, an antibody, and the drug moiety, including a camptothecin drug moiety, as of November 5th, 2014.

Doctor Toki has explained how the '039 Patent has an adequate written description testifying that, first, the specification of the '039 Patent discloses multiple tetrapeptide sequences that together directs a POSA toward a tetrapeptide of only Gs and Fs. For example, the '039 Patent includes the exemplary sequence GFLG from which a POSA would be able to visualize a tetrapeptide made up of only Gs and Fs.

Furthermore, together with what we already -- what was already known in the art as of the filing date of the '340 application in 2004, a POSA would also be aware of existing

tetrapeptide sequences made entirely of glycines and phenylalanines, and understood that the use of phenylalanines in the P2 position would make intracellular cleavage more favorable.

Doctor Bertozzi testified that the specification of the '039 Patent discloses a large number of drugs that can be used in an ADC, including camptothecins, and describes how different drugs can be attached to an ADC via different chemical groups.

Defendants failed to prove -- I'm moving on to enablement, Your Honor.

THE COURT: That's fine.

MR. COHEN: Defendants failed to prove by clear and convincing evidence that the '039 Patent is invalid for lack of enablement under 35 U.S. C. § 112, and no reasonable jury could find otherwise.

Again, Doctor Lambert admitted he did not apply the correct standard to assess the validity of the '039 Patent for purposes of his lack of enablement contention, Doctor Lambert did not review the evidence with the understanding that the patents have a presumption of validity, and did not understand invalidity needs to be shown by clear and convincing evidence. Doctor Lambert also admitted it would be routine to make tetrapeptides and that it would be easy to make a tetrapeptide of Gs and Fs.

Dr. Peter Senter confirms that making peptide sequences is routine. Doctor Lambert conceded that as of the filing date of the patent in 2004, the patent application in 2004, many different drug types had been successfully attached to an ADC.

Dr. Peter Senter and Doctor Toki also confirmed they have created working ADCs with many different drug types and that such experimentation is routine.

Doctor Lambert did not sufficiently explain why it would require undue experimentation to determine intracellular cleavage.

Dr. Toni Kline, an inventor listed on the '039 Patent, testified that there are routine assays that could be used to determine intracellular cleavage of ADCs.

The testimony of Seagen expert Doctor Bertozzi, relying on the specification of the '039 Patent and documents establishing the state of the art and other enablement factors, as well as the testimony of other fact witnesses, establish that a person of ordinary skill could make and use the full scope of inventions of claims 1 to 5 and 9 and 10 without undue experimentation as of the filing date of the original application in November 5th, 2004.

Doctor Bertozzi's testimony demonstrated that the '039 Patent enables the skilled artisan to make and use ADCs meeting all of the limitations of the asserted claims, which

includes a tetrapeptide linker consisting of only G and F amino acid residues, an antibody, and a drug moiety, including a camptothecin drug moiety, as of November 5th, 2004.

Doctor Bertozzi also gave testimony demonstrating the following: Making amino acid sequences, including tetrapeptides, is routine and does not require undue experimentation.

Doctor Bertozzi confirmed that as of the filing date in 2004, tetrapeptides of Gs and Fs were known in the art, and a POSA would have known that using phenylalanines in the second position, P2, could improve cleavability of the amino acid sequences. A POSA would know how to conduct the appropriate chemistry to attach various drugs to an ADC via different chemical handles.

Doctor Bertozzi explained that the chemistry needed to attach various drug types, including camptothecins, had been known for decades, and that such chemistry is regularly taught in a freshman college chemistry course. Doctor Bertozzi confirmed that attaching various types of drugs in an ADC does not require undue experimentation.

Defendants have failed to prove their anticipation defense, and no reasonable jury could find otherwise. For the same reasons previously stated, with respect to the failure of Defendant's inadequate written description and lack of enablement defenses, Defendants failed to meet their burden

that the '039 Patent should not be accorded priority to U.S. Patent Application No. 10/983,340.

Doctor Lambert conceded that he failed to apply the appropriate legal standard for his analysis of whether the '039 Patent is anticipated. He further testified that the Ogitani reference from 2016 that he relied on for his anticipation analysis was the same reference that the patent examiner examined during prosecution of the '039 Patent's application before she issued the patent.

As a result, Plaintiff is entitled to priority to the filing date of the '340 application, which is November 5th, 2004, under 35 U.S.C. § 120. All of the prior art Doctor Lambert testified about is dated after 2004.

As a result, Defendants have failed to establish anticipation as a matter of law.

THE COURT: Thank you.

Anything further on these topics? I guess not.

MR. COHEN: Sorry.

THE COURT: I'll ask again, anything further?

MR. COHEN: Nothing further on the § 112, and anticipation defense by Defendants.

THE COURT: All right. Thank you.

Mr. Fletcher, what argument does Defendant care to put forward on these topics?

MR. FLETCHER: I'll just try to be brief, Your

Honor. We've addressed several of these in our written motion.

I'll just start with the concession that opposing counsel made that the POSA would be able to visualize the G/F-only tetrapeptides based on their skill and what they understand and from what they read in the disclosure of the 2004 application. That is not enough as a matter of law. There is the *Goeddel v. Sugano* case from the Federal Circuit in 2010 that makes this abundantly clear, because that is exactly the standard that the PTAB--I guess maybe it was a different entity at that time--had applied in an interference, and the Federal Circuit reversed saying it is not enough for the POSA to be able to envision; you have to actually disclose your invention. And the entirety of the evidence we've adduced over the past four days, I believe, would show, Your Honor, that there is no disclosure of any G/F-only tetrapeptides. So we get judgment as a matter of law with regard to priority.

Once there is no priority to the 2004 application, and the patent is entitled only to the 2019 filing date, there is judgment a matter of law of anticipation in the event of a finding of infringement, because there is no testimony adduced by the Plaintiffs with respect to the Ogitani reference and its disclosure. Doctor Lambert's testimony concerning it stands unrebutted, and the cross examination of Doctor Bertozzi about it stands unrebutted.

With respect to the enablement points, just briefly, Your Honor, Doctor Lambert laid out in great and unrebutted detail that even to this day it is impossible to generalized how to assay for intracellular cleavage, and under the Federal Circuit's *Gilead v. Idenix* case, and the stand's they've elucidated for undue experimentation involved in screening, it doesn't even matter if it's routine to perform the assay or routine to make the product. Even then, undue experimentation is required when you can't figure out the scope of the massive genus.

With respect to being able to make all the ADCs, there is also I think unrebutted testimony that these are complicated molecules. These ADCs are very challenging molecules. So the fact that there's testimony that it's easy to make a tetrapeptide or easy to make a drug is not enough. What they needed to adduce was testimony that it was routine to make the ADCs. Doctor Lambert showed, convincingly, that there are all manner of ADCs that could not be made because the drugs could not be connected to a linker as of 2004.

And finally, with respect to the written description concerning the drug moiety in the ADCs, I think the trial record is replete with the fact that the invention disclosed in the 2004 application and the '039 Patent is ADCs made with monomethylvaline compounds, those auristatins that we heard about over and over throughout the trial record. I think most

significant of all was Doctor Toki's testimony that what he thought he invented was the auristatins, not ADCs made with any drug.

I think that suffices.

THE COURT: Thank you, counsel.

Let me hear from Defendants with regard to their motion concerning willful infringement, and then I'll hear from Plaintiff in response.

MR. FLETCHER: Certainly, Your Honor. This is laid out in more depth in our written motion, Docket 365, but in short, the willfulness standard is one of egregious, wanton conduct, and what the record shows here is that Daiichi Sankyo publicized that it was developing Enhertu in 2015, it filed for approval from FDA to bring Enhertu to market in 2019, it brought Enhertu to market on an accelerated basis, and then it got sued for infringement in 2020. It has continued to provide Enhertu -- that Daiichi Sankyo, Inc., that is, has continued to provide Enhertu to patients, and we heard unrebutted testimony from Doctor Ko about what a tremendous drug it is for extending the lives of patients with metastatic stage four breast cancer. The idea --

THE COURT: Slow down just a little bit, Mr. Fletcher, please.

MR. FLETCHER: Certainly, Your Honor. My apologies.

The idea that there is anything egregious or wanton or

willful about any of the conduct that is accused of infringement in this case is untenable.

THE COURT: Does Plaintiff have responsive argument with regard to the willfulness issue?

MR. COHEN: Yes, Your Honor.

We oppose the motion. There was no request by Daiichi Sankyo for a license when this patent issued and it continued to sell Enhertu within the United States. Instead of paying us a royalty, Daiichi Sankyo to continue to sell Enhertu in the United States with authority under a license from Seagen, it decided it would infringe.

We also heard substantial evidence during the trial on willfulness. We heard testimony and we saw documents about the Seagen collaboration with Daiichi Sankyo and how the information from the collaboration ended up being used for Daiichi Sankyo's internal and secret development processes for ADCs in its working group, and how that information made its way to the project specifically to design Enhertu and manufacture Enhertu.

And Daiichi Sankyo continued to sell the product without a license, despite knowing that it had taken Seagen's information that it had received during the collaboration and used it to help develop Enhertu.

That's all I have, Your Honor.

THE COURT: Thank you.

Let me hear from Defendants with regard to their damages issue under Rule 50(a).

MR. FLETCHER: Certainly I'll be brief, Your Honor.

The judgment as a matter of law we request on damages would be if there was liability, no reasonable jury could award more than a two percent royalty because Ms. Distler's testimony did not account for the other patents that are included in the licenses that she analyzed and on which the entirety of her analysis was based. The Federal Circuit's recent precedent in *Apple versus Wi-LAN*, it's controlling authority that indicates that you cannot perform an analysis of the type that Ms. Distler did where you don't take into account the value of the other patents that are included in the licenses. With that, the only testimony in the record that's premised on a proper evidentiary basis is Doctor Meyer's analysis, and as she told the jury, the appropriate royalty range would be between one and two percent.

THE COURT: All right. Mr. Cohen, what's the Plaintiff's response?

MR. COHEN: Our view is our damages expert Ms. Distler applied and presented a damages opinion of five to eight percent supported by substantial evidence. She -- and proper as a matter of law. She applied the *Georgia-Pacific* analysis and factors. She properly apportioned in her testimony and in her economic analysis of the agreements for

the value of the '039 Patent as compared to unpatented features, including other patents.

We saw her final analysis when she described how she got to her royalty range; that she applied a reducing factor to account for the fact that the license in the hypothetical negotiation would be a non-exclusive license to a single patent as opposed to some of the other agreements; that she analyzed for their economic importance extensively.

She described to the jury how she evaluated the relevant agreements as well as the ADC market and the other facts and circumstances in detail to develop her royalty opinion, and we believe Defendants are wrong on the law as to the value of her opinion.

Thank you, Your Honor.

THE COURT: All right.

Has the Court overlooked anything from either party with regard to practice under Rule 50(a)?

MR. FLETCHER: No, Your Honor.

MR. COHEN: No, Your Honor.

THE COURT: All right. With regard to the motions that have been urged, particularly covering the areas of direct and indirect infringement, including particularly induced infringement as well as the areas of invalidity urged both under § 102 and § 112, as well as arguments -- competing arguments regarding the asserted 2004 priority date,

anticipation, enablement, and written description, and concerning the motion under Rule 50(a) addressing willful infringement and damages as asserted by the Plaintiff, these motions and all matters raised by the parties under Rule 50(a) are denied.

Now, I'm going to release Mr. McRoberts and Ms. Brunson and we're going to proceed with an informal charge conference. I had earlier thought, counsel, it would be appropriate to do this in my chambers, but I'm comfortable where I am and I see no reason why we can't just do it where you are, but we don't need the court reporter or the Courtroom Deputy.

I don't know what the status with the CSOs is. I'm not afraid of any of these people, Mr. Latham, physically or otherwise. But if you need to stay, I know you have certain guidelines you have to follow. Okay?

And I do mean sincerely I want to have free-flowing and helpful input from the parties. If you're not involved in this there's no reason for you to stay.

(The proceedings were concluded at 6:35 p.m.)

I HEREBY CERTIFY THAT THE FOREGOING IS A CORRECT TRANSCRIPT FROM THE RECORD OF PROCEEDINGS IN THE ABOVE-ENTITLED MATTER. I FURTHER CERTIFY THAT THE TRANSCRIPT FEES FORMAT COMPLY WITH THOSE PRESCRIBED BY THE COURT AND THE JUDICIAL CONFERENCE OF THE UNITED STATES.

S/Shawn McRoberts 04/07/2022

_____DATE_____

SHAWN McROBERTS, RMR, CRR
FEDERAL OFFICIAL COURT REPORTER